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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91215699
Party	Plaintiff Boston Scientific Corporation, on behalf of itself and its subsidiaries, Asthmatx, Inc.
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Signature	/Timothy D. Sitzmann/
Date	08/05/2015
Attachments	Deposition Transcript - Karen Passafaro - Redacted - Full with signatures.pdf(2948598 bytes) Segment 001 of Deposition - Karen Passafaro - Non-Confidential Exhibits.pdf(5215238 bytes) Segment 002 of Deposition - Karen Passafaro - Non-Confidential Exhibits.pdf(5198503 bytes) Segment 003 of Deposition - Karen Passafaro - Non-Confidential Exhibits.pdf(4003570 bytes) Deposition Transcript - Matthew Sprague - Redacted - Full with signatures.pdf(405907 bytes) 20150805 Certificate of Service - Passafaro and Sprague Transcripts.pdf(44287 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Opposition No. 91215699

In the matter of Application Serial No.:
85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
Published in the Trademark Official Gazette
on December 3, 2013

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Boston Scientific Corp. and
Asthmatx, Inc.,

Opposers,

v.

Holaira, Inc.,

Applicant.

****

DEPOSITION OF KAREN M. PASSAFARO

Thursday, April 9th, 2015

8:50 a.m.

Held At:

Latham & Watkins, LLP

200 Clarendon Street

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR #149108

APPEARANCES:

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OPPOSER EXHIBITS

APPLICANT'S EXHIBITS

P R O C E E D I N G S

KAREN M. PASSAFARO,
having been first duly identified and sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. WALZ:

Q. Karen, good morning.

A. Good morning.

Q. Just before we get into this, I want to just let you know a little bit about the format, how it's going to happen today.

Dennis and I had a discussion and so -- and had made an agreement that what will happen is I'm going to have a direct examination of you, and then when I've completed my direct examination, Dennis will have an opportunity to cross-examine you, and then following his cross-examination I will have an opportunity to redirect. So just so you're aware, that's going to be the format for today.

If at any time, you know, you want to take a break, just let us know. I'm amenable to taking breaks whenever the witness is. I don't know if --

MR. WALZ: Dennis, do you have a problem with that?

MR. HANSEN: I think just the one caveat to that is if there's a question pending, the witness should answer the question pending before we take a break. But otherwise, absolutely we can take a break whenever.

BY MR. WALZ:

Q. So just let us know whenever you'd like to take a break and we'll do that.

As you notice, we have a court reporter here, and so she's going to be taking down your testimony today. When you're responding to a question yes or no, make sure it's a yes or no, not a yah, so that it's just clear for the record.

So with that, I think we can begin.

A. Okay.

Q. Can you say and spell your name for the record?

A. Karen Passafaro, P-A-S-S-A-F-A-R-O, Karen, K-A-R-E-N.

Q. And what's your educational background?

A. So I have a bachelor of science in

bioengineering from UC-San Diego, University of California-San Diego, and an MBA from University of Phoenix.

Q. And what was your work experience prior to Boston Scientific?

A. So I joined Boston Scientific in 2010 as vice-president of marketing. Prior to that, I was vice-president of marketing for Asthmatx. So basically with the same job and the same function, Boston Scientific acquired Asthmatx, so I've been basically doing this job for the last ten years, since 2005.

Q. And so what was your position, your first position at Boston Scientific?

A. Vice-president of marketing.

Q. Has it always been vice-president of marketing?

A. Yes.

Q. And your duties as vice-president of marketing, what are those?

A. So I manage the Bronchial Thermoplasty franchise within the pulmonary group, which is part of the endoscopy division of Boston Scientific, they're based here in Marlborough, and I'm responsible for the global marketing of

the Bronchial Thermoplasty franchise.

Q. Turning now to the Alair market, who was responsible, or who created the Alair mark?

A. Asthmatx.

Q. And what was the process for selecting the Alair mark?

A. So it was created in like 1999, and it was a typical process for a trademark or a product name. It was created prior to my joining Asthmatx. A group looked at a number of different names, you know, did -- bounced ideas off, and then selected a name, and then had our -- they had the legal team do a trademark search.

Q. And why was the Alair mark chosen?

A. So Asthmatx was formed to create a product to relieve asthma sufferers, so the product was always focused on asthma, severe asthma, and opening up the airways to allow people to breathe easier. And Alair, or "all air," kind of had that connotation of improving air -- you know, increasing airflow, and that resonated with asthma patients who had the constriction of their airways.

Q. And when was the Alair mark adopted?

A. I believe it was 1999 was when the mark was chosen, and I believe that's when the legal trademark was filed.

Q. Okay. Has the mark continuously been used?

A. Yes. It was -- the product was -- in '99 it was in a preclinical, you know, R&D testing, and then clinical trials started in around the 2000 period. All of the clinical trials that Asthmatx did used the Alair product, and that name has been in existence continuously and through FDA approval and the commercial launch of the product. The name has been consistent.

Q. And how did Boston Scientific come to own the Alair mark?

A. So Asthmatx got FDA approval in 2010. At that point Boston Scientific made a bid for the company, and acquired us in October of that year, October, 2010, after we were commercially -- FDA-approved and commercially on the market.

Q. Okay.

A. And Boston Scientific acquired the company, the product, and all the trademarks.

Q. So what good or goods is the Alair mark used in connection with?

A. So it's the Alair Bronchial Thermoplasty system is the full name of the product, if you will. So there's the Alair controller, which is a piece of capital equipment that delivers RF to the Alair Catheter, which is a single use disposable that is used through a bronchoscope, and together the catheter, the Alair Catheter and the Alair controller compose the Alair Bronchial Thermoplasty system.

Q. Okay. And why is the Alair mark used to identify both the system and the individual components?

A. Because you need both pieces of equipment to do the therapy. You need the controller to deliver energy, and you need the catheter. It also, from a user instructions, it was helpful to be able to call out specifically a catheter -- the Alair Catheter plugs into the Alair controller. And also, to avoid any type of misuse of either the catheter or controller being used with someone else's controller or catheter or generator. We, for safety reasons,

we wanted to make sure that the two, the catheter and the controller, were always used together. The concern of having somebody develop a knockoff catheter that might be used with our controller, we wanted to avoid that.

Q. And what are the current indications for the Alair System?

A. So in the United States, the FDA indication is for adults with severe asthma that are on standard medication, which is ICS, inhaled corticosteroids, and long-acting beta agonists, or standard medication, and those patients are still symptomatic.

Q. Okay. And what are the prospective indications for the Alair System?

A. Meaning potential indications or future?

Q. Or potential, yes, future.

A. There definitely has always been plans for potential clinical studies going into the pediatric market, so the 12 to 15, 12 to 18-year-old, and also looking into patients with asthma and COPD.

Q. Okay.

A. Or chronic obstructive pulmonary

disease. I don't know if I should talk in acronyms.

Q. COPD is short.

And what services or service is the Alair mark used in connection with?

A. So in addition to the product itself, we also do a lot of training. So physician training is very important. Training physicians, staff, nursing, anesthesiology in the use of the product, and so we use the trademark for the training services that we provide as well.

Q. What do the training services entail?

A. Use of the product, you know, a full product inservice, if you will, on how to use the catheter, how to hook it up to the controller, what are the right indications for the patient, patient management, how should a patient be, you know, sedated and, you know, prior to the procedure pre-op, post-op type of training.

Q. Okay. And how do you market those training services?

A. So we have a direct sales force with Boston Scientific that is around the world,

typically. And the sales reps will work with the physicians who are interested in performing the procedure, and then work with their hospital, who is the ultimate purchaser of the product, and they will, you know, arrange for training programs, you know, when the physicians are interested in getting started with the procedure.

Q. And how long has the Alair mark been used in connection with teaching in the training services?

A. A lot of the training was actually started in our clinical trials, so that started around 2000. And then from a commercial standpoint, in 2010, in May of 2010 was when we started to, you know, actually sell the product after FDA approval. It's been used continuously since that time.

Q. Okay.

A. And it started with Asthmatx. And then when we were acquired, Boston Scientific continued with the same training. The programs and training systems that we had put in place, Boston Scientific continued that same training, and actually expanded it to now over 30

countries.

Q. So does Boston Scientific have a marketing plan or strategy for the Alair System?

A. Yes.

Q. And what is that marketing plan or strategy?

A. So it's to grow the business, and increase revenue obviously. We look at number of controller placements and new controller sales, and then look at repeat catheter business around each of those controller sales, if you will.

[redacted]

Q. Okay. And who developed the marketing plan or strategy?

A. I did.

Q. And who is responsible for the

marketing budget?

A. I am.

Q. And as you're coming up with the marketing plan or strategy, what factors do you consider when developing the strategy?

A. [redacted]

We'd also look at where we were from a data standpoint, what new data was coming out, and how we would want to promote that data, so that would affect the marketing plan and the budget.

We would look at potential competition and what was the competitive landscape at the time. That could weigh into the budget, of course.

And then we'd look at, you know, just market dynamics. If there was -- you know, from a society standpoint we'd look at were we getting endorsements from the societies, were we getting reimbursement or insurance coverage approvals. That would also affect our ability to spend in marketing based on what we expected our revenue could be.

Q. And how would you define the market for the Alair System?

A. Our market is for the severe asthmatic who is still symptomatic, so adults, severe asthma, and symptomatic. More specifically, our market is a device-based therapy for asthma, so devices to treat asthma is our core market.

Q. And you had mentioned earlier that you consider competitors in developing your marketing plan?

A. Yes.

Q. So what competitors does -- well, I guess what competitors does Boston Scientific

have for the Alair System?

A. At this time we have no direct competitors in the device business for severe asthma.

Q. Are you aware of any medical devices under development that could potentially compete with the Alair System?

A. Yes.

Q. And what device would that be?

A. That would be the device developed by Innovative Pulmonary Solutions, now known as Holaira, a device using RF energy focusing on COPD, but it's very possible that that device could also be used in asthma.

Q. So what are the similarities between the Holaira device as you know it under development and the Alair System?

MR. HANSEN: Object to foundation.

BY MR. WALZ:

Q. You can answer.

A. So my understanding is that it's definitely a catheter-based system that attaches to a controller, I believe it's RF energy, and they're ablating or using heat to treat the nerves within the airway. It's done

bronchoscopically. It's performed by a bronchoscopist or a pulmonologist who specializes in bronchoscopy, very similar, the exact same customer base, so very similar mechanism and process for a device.

Q. And all that detail you just testified to with respect to the Holaira device, how do you know that?

A. Having seen directly a presentation at the European Respiratory Society meeting in September, the company presented their information, presented the clinical data, presented, you know, a pretty in-depth slide presentation on how it works.

Also the physicians that are doing the procedure, the early feasibility studies, I know those physicians very well and speak with them often. They were in our clinical trials as well.

Q. And what similarities exist between the Holaira mark and the Alair mark?

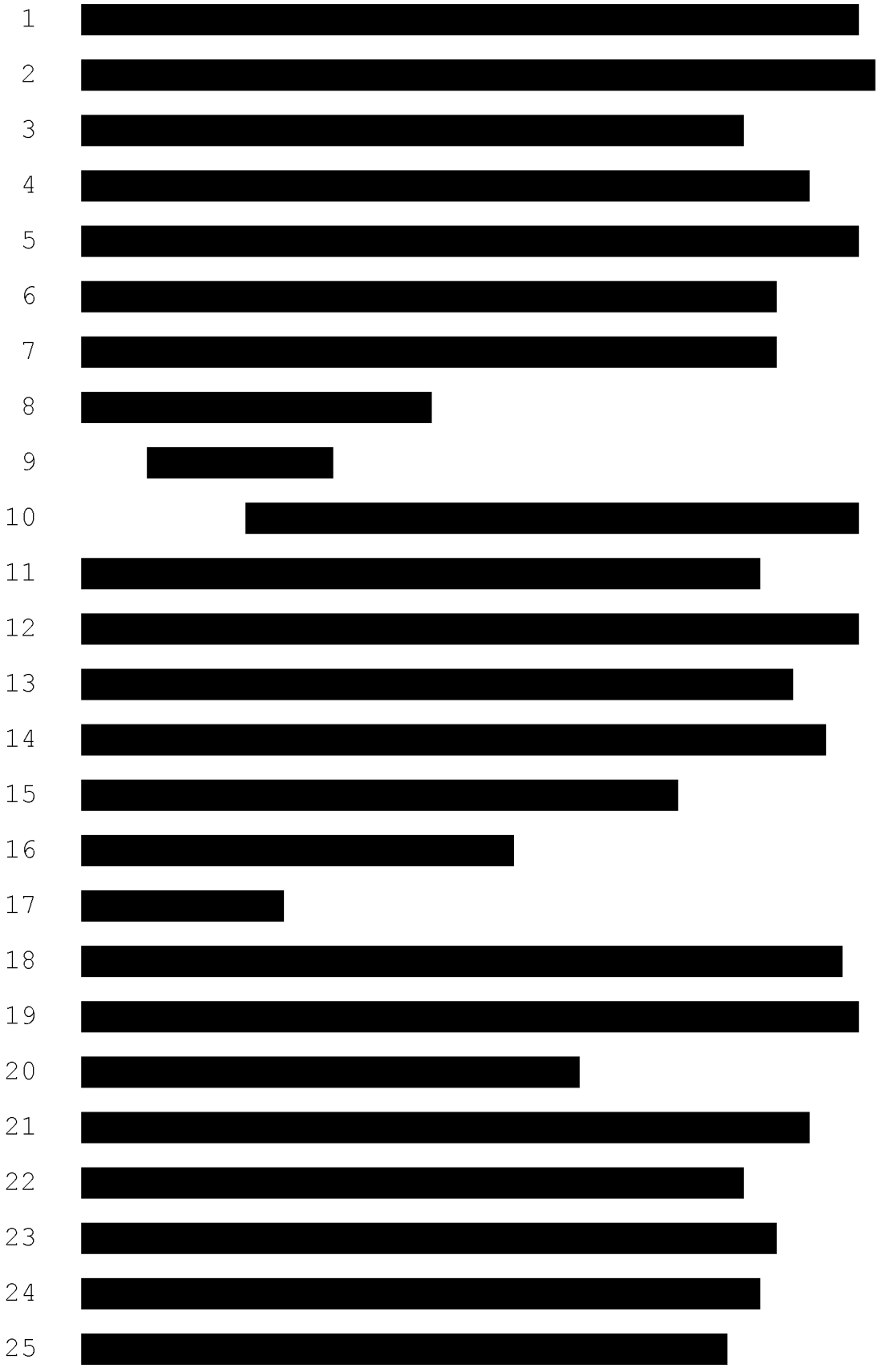
MR. HANSEN: Object to foundation. Object to the extent it calls for a legal conclusion.

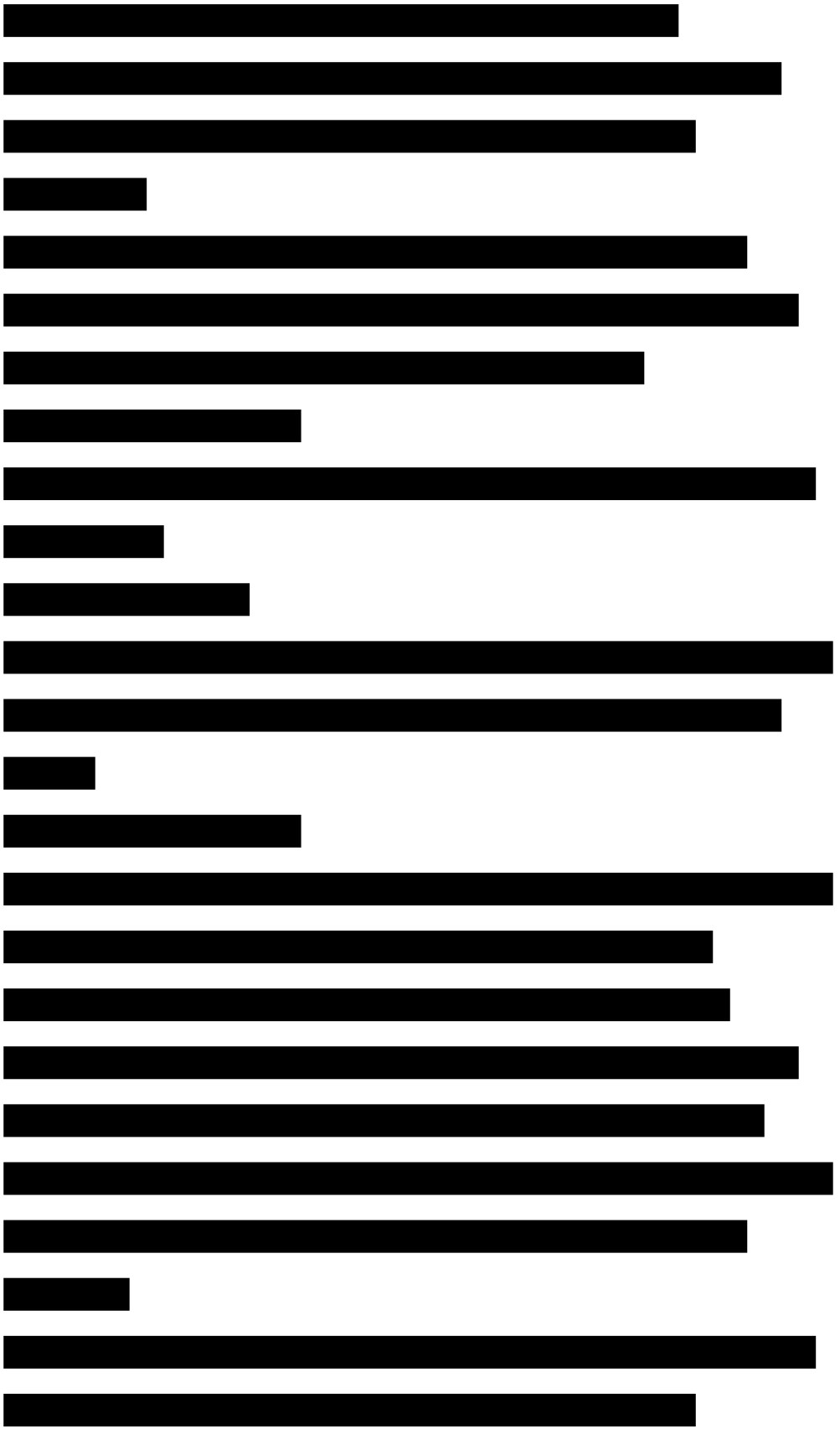
A. So I think just the names are very

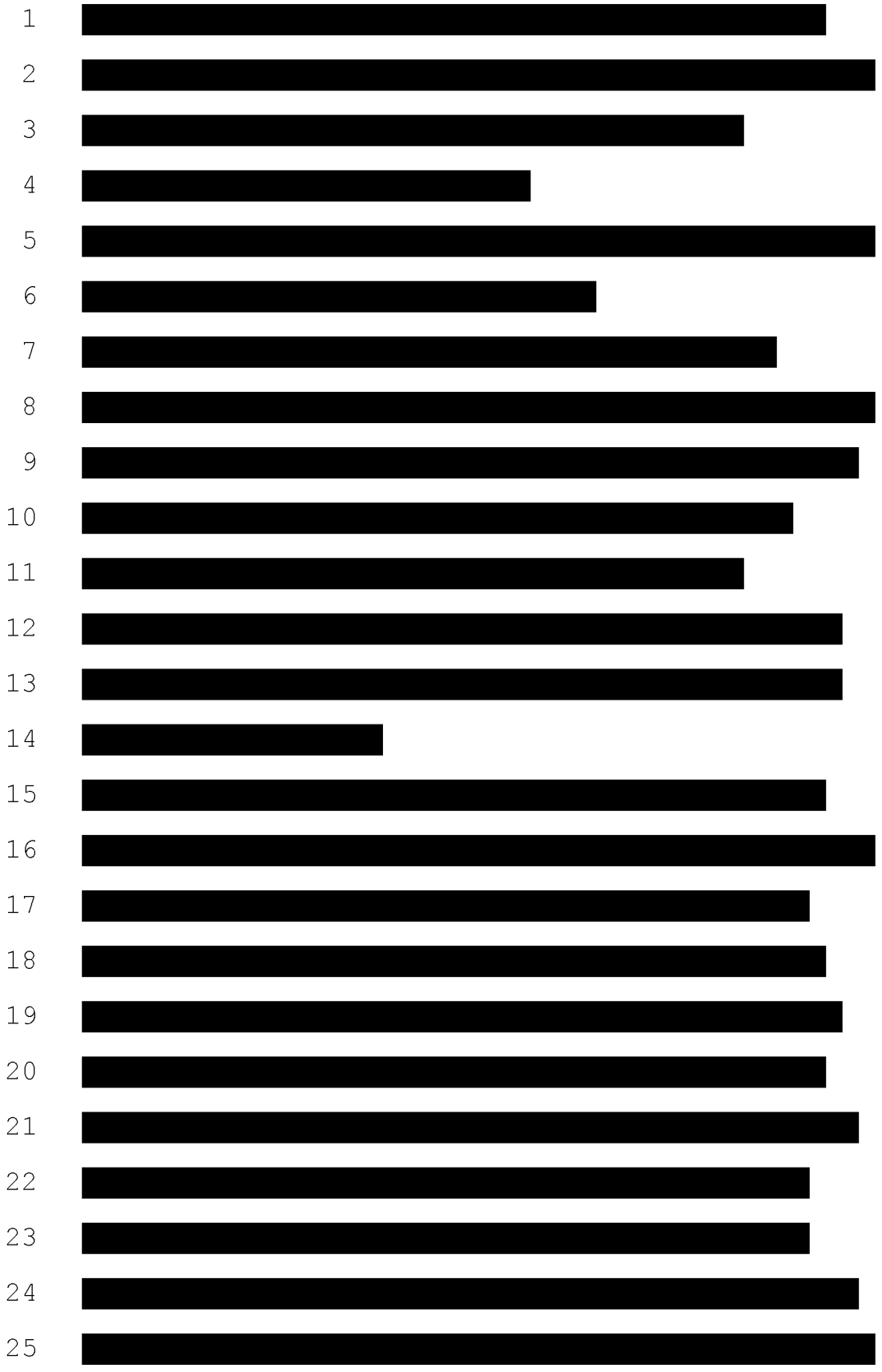
similar. You know, Alair and Holaira sound very similar. I thought it was interesting, the name came about only in the last few years. The company started as IPS, that's how we always referred to the company, as IPS, and then the company changed the name around 2011, 2012, I think, right as we were kind of really getting pretty broad spread use of the Alair System. It was -- we all noted that it was kind of odd to have such a different name change to something that was so similar to a product that was now commercially available.

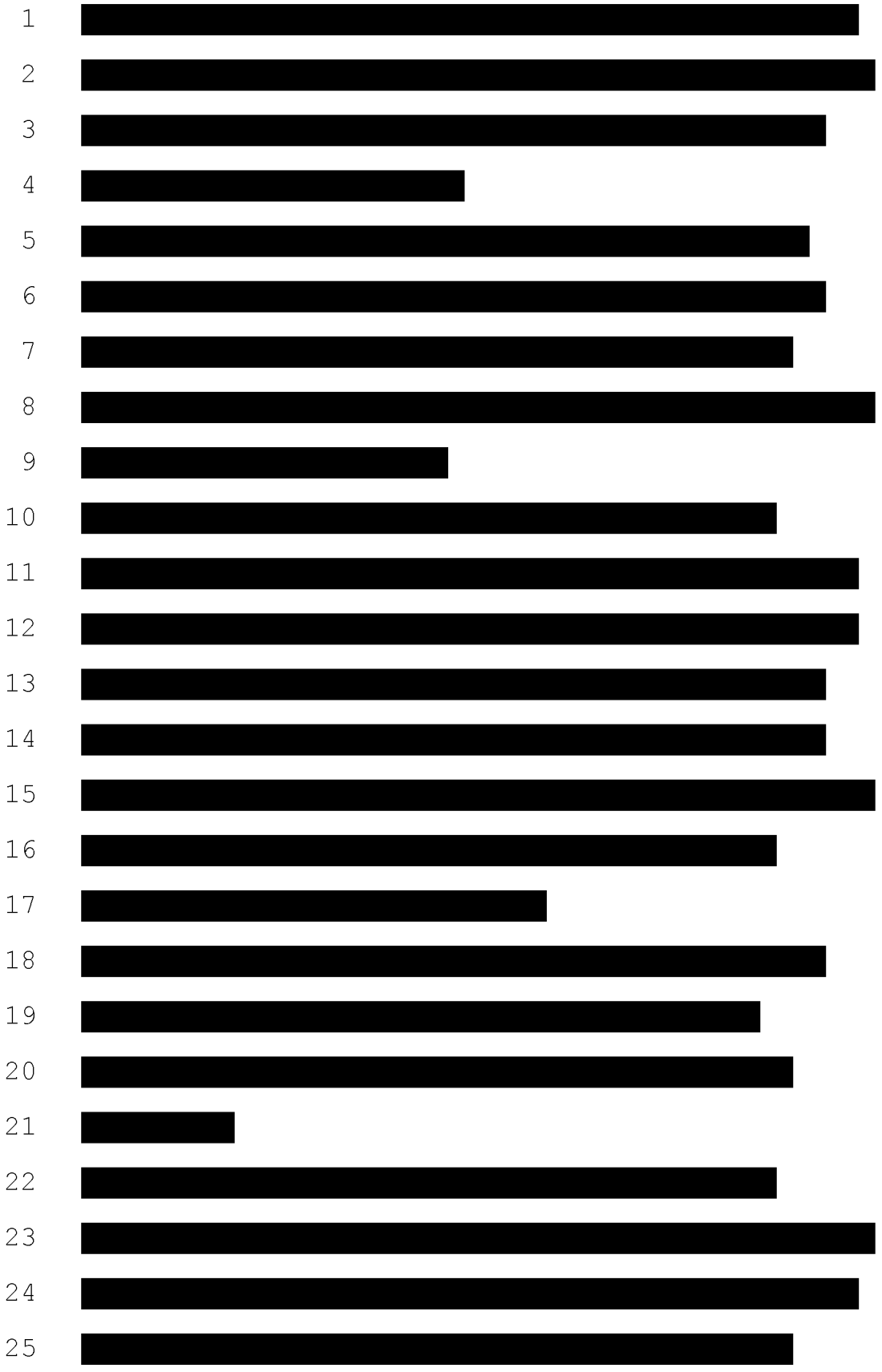
Q. How is the budget prepared, the marketing budget referred to, how is that prepared at Boston Scientific?

A. [redacted]









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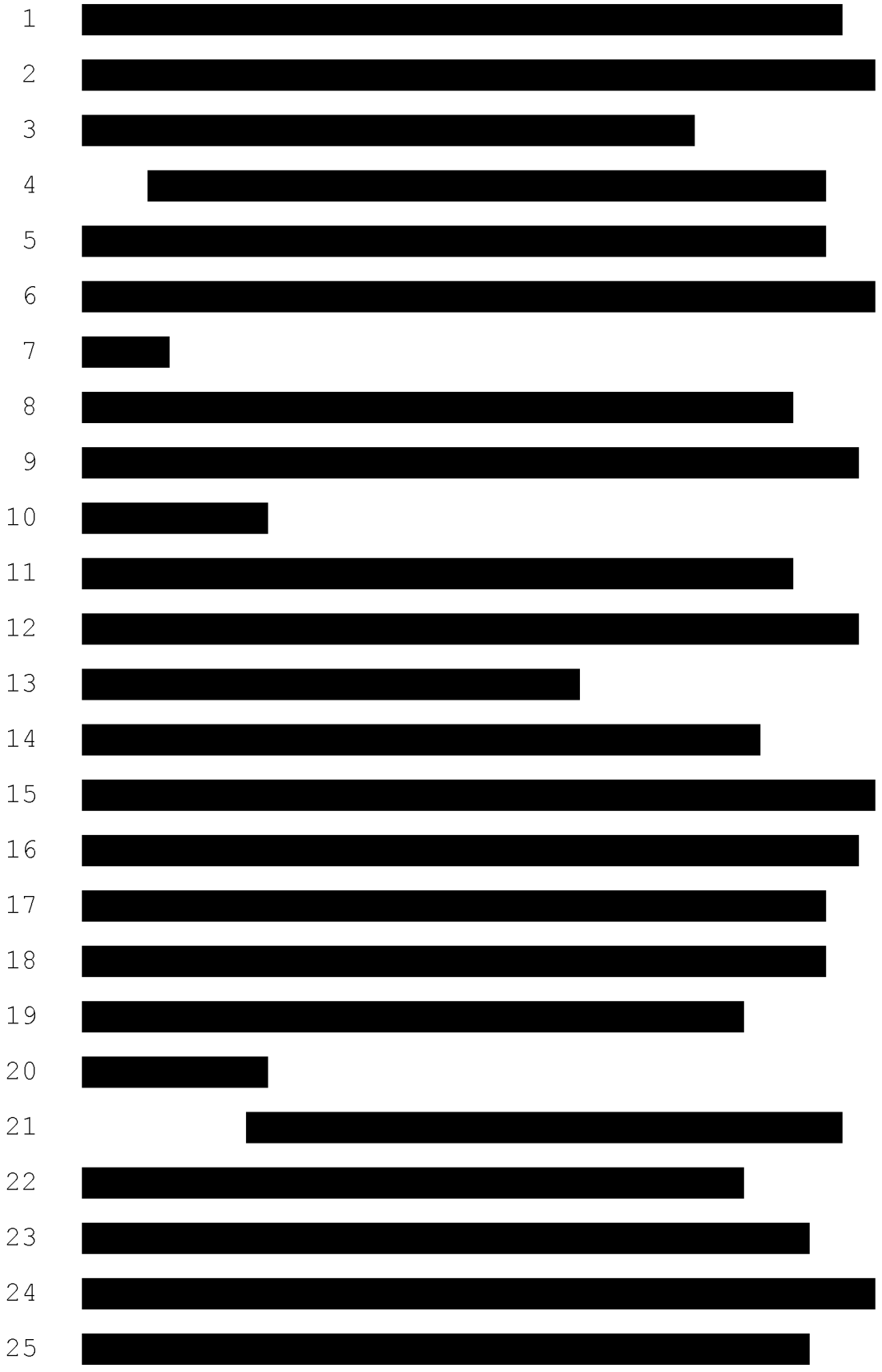


[redacted]

Q. Can you explain the reimbursement portion of the marketing in a little more detail, what that entails?

A. So reimbursement is really focused on insurance companies and getting, you know, coding, coverage, and payment. So first you have to have a CPT code that a physician and a hospital can use to bill. We -- that group was behind all the efforts to get a CPT code for the Alair System, and that happened, I believe, in 2012.

And then once you have coding, then your big focus is on coverage, and so that's making sure that all of the large payers in the United States, and we deal with over 100 different insurance companies, that they know the data, that they know the safety and the

efficacy, and they know all about the product and the benefits of the product. And so we have a team of people that are focused on making payers aware of it, and then they're also working with the physicians locally to help them maneuver through the reimbursement process. So if Blue Cross/Blue Shield doesn't cover it, then the patient and the physician have to ask on a case-by-case basis. So we have a team of people in the corporate office, as well as five people in the field that are supporting the reimbursement.

So it's often looked at as kind of a marketing expense because it's helping the physician gain approval to then treat that patient and have the hospital buy the catheters.

Q. You mentioned that Boston Scientific acquired or obtained a CPT code?

A. Correct.

Q. So what's required to obtain a CPT code?

A. So clearly the FDA approval, it has to be proven safe and effective, it needs the support of the society that will ultimately be providing that procedure or that service, in

this case it was the American College of Chest Physicians and the American Thoracic Society, and we'd been working with those societies, you know, even before our FDA approval, making sure that they were aware that it was coming and what it was and how it worked.

And then the society has to recommend that this code be added to the American Medical Association or the AMA. They control CPT codes. And so to do that, you also have to prove that you have widespread use, that this is a common procedure, that it's used across the country, it's not experimental, it's not only in, you know, academic medical centers, if you will. And so we -- within our first year after FDA approval, we had well over 100 centers that had purchased the equipment and were providing the procedure. So that all went in together to support the ACCP and the ATS societies to then submit for a CPT code, which was granted, I think, in 2012 or early 2013.

And I will say that because that CPT code was accepted, that was another reason why we kind of dialed up the marketing expense in 2013. Because with the CPT code, we felt that

we had the wind behind our sails a little bit with coverage, and that would then start the domino effect with coverage would happen, and it just hasn't happened yet.

Q. What are you waiting for for it to happen?

A. [redacted]

Q. So what are the normal marketing channels for the Alair System?

A. So we market to both physicians and patients, so we use a customized website as one of our primary focuses. We do print, we do digital, we do direct-to-patient, direct-to-physician, podium presentations, advertising in all the major journals, the

Thoracic Society and the allergy societies. There's four major journals. We push to get publications about the device in those journals, you know, case studies, not only the data that Boston Scientific has done in our clinical trials, but we work with other physicians around the world to encourage them to publish case studies and case series about their procedures and their results.

We've got a direct sales force in the United States, so they're working directly with the physicians, educating them. You know, a lot of PowerPoint presentations. We have a computer simulated type of training program that we use for training, you know. DVDs, a lot of PowerPoint presentations at the hospital level with nurses. We've supported a lot of American Lung Association patient events, so we'll support regional small exhibits, and society meetings as well.

(Whereupon, Opposer Exhibit Number 3, Copy of marketing flyer, Bates BSC000834 through 836, was marked for identification.)

BY MR. WALZ:

Q. You've been handed what's been marked as Deposition Exhibit Number 3.

A. Mm-hmm.

Q. Do you recognize that exhibit?

A. Yes. This is a flyer for a patient.

Q. And where would this flyer have been distributed?

A. So this would be used -- physicians could hand this out to patients in their waiting rooms. If a patient was interested in being treated with the Alair System, the physician might offer this. This could have been used at patient events. I mentioned the American Lung Association, we do a lot of lung walks and asthma walks. And so things -- health fairs where there might be all kinds of different vendors that are there for different health things. We might do -- this would be handed out to catch the attention of asthma sufferers. You can see that "asthma attacks" was bolded, our market research told us that that's what the patients were going to focus on, or would catch their attention.

Q. And what was the circulation number or number of impressions that this flyer made?

MR. HANSEN: Object to foundation.

A. You know, we probably printed, you know, 100,000 of them. I wouldn't know the impression number, just printing number.

BY MR. WALZ:

Q. How would you know that printing number?

A. Based on purchase orders, what we printed. So we print and then distribute them to sales reps in doctors' offices. But with print, it's not as easy to know exactly how many people see it.

Q. And how do you know the effectiveness of this flyer?

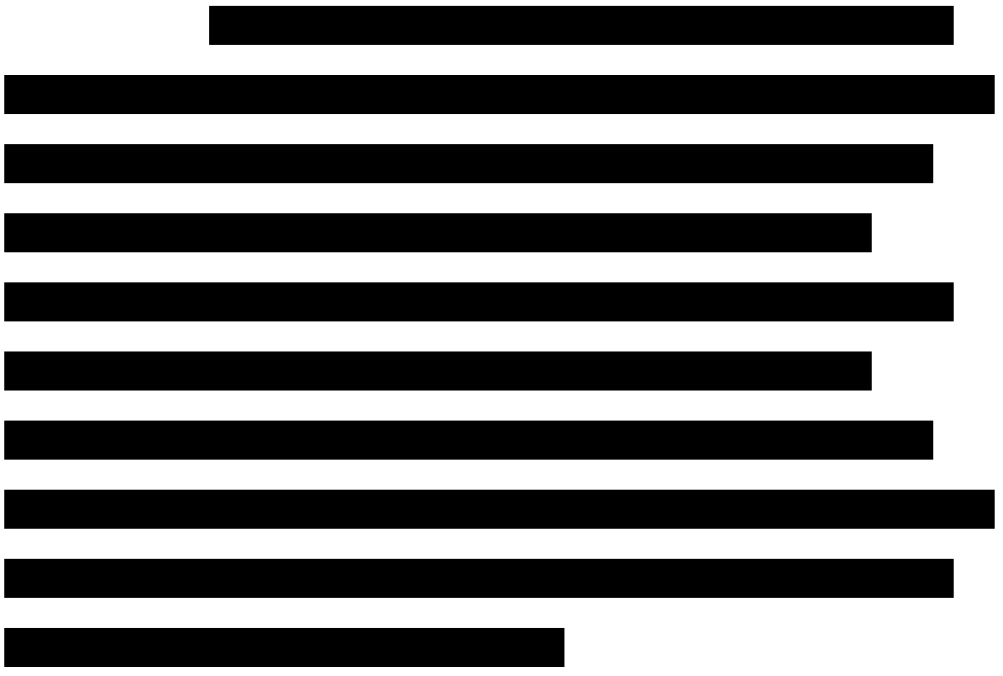
A. Based on our direct conversations with physicians and their comments about the information here, the fact that they, you know, have asked and continue to ask for these flyers to share with their patients. Our sales reps through direct interaction with patients at these health fairs, you know, we get continual feedback of what is it that the patient is really wanting to learn about.

So -- and clearly this is kind of an initial information. Obviously there's a lot

more information about the procedure we want the patient to learn, so we typically in all of our materials for patients, we direct them to our website where they can find out much more about the procedure in a multimedia format.

Q. I guess what goes into -- what planning, or what goes into creating a flyer like this?

A. So we start with, you know, what are the objectives of the piece? Who are we trying to reach? Who are we trying to educate? What do we want to convey to them? What is the information? We look at based on the audience, you know, what's enough information, what's too much information.



Q. So you'd mentioned that this flyer would have been distributed at a trade show, for example?

A. Could have been trade shows, physician trade shows, patient events, you know, large health fairs. A lot of times we'll support a hospital's health fair, they have a health fair on a Saturday and they have vendors there at the hospital, those type of events, this would be used at any of those.

Q. So what trade shows did you -- or did Boston Scientific attend, for example, in 2011?

A. So from 2010 until now, we attend four major trade shows, I would say national trade shows. The American College of Chest Physicians is one, that's called CHEST; the American Thoracic Society, that's the ATS; the Asthma, Allergy and Immunology meeting, it's called AAAAI, for A's and an I, that's the Academy meeting for allergy; and then the College meeting for allergy, which is ACAAI. A lot of vowels.

So there's two major pulmonary meetings and two major allergy meetings, and we've exhibited at all four of those for the

last six years. Those are national meetings, international actually, with large attendance at each one.

And then in addition to that, we have a mechanism where we submit to support regional meetings. So we would support the Florida Allergy Society, the Greater Cleveland Allergy Society.

We have a grant committee, that these requests come in to a grant committee and we look at the agenda, we look at the audience, we look at the location of the meeting, and if we feel that it's a solid educational program, you know, we would support through a small exhibit. Those are typically one or two-day smaller regional meetings, and these would be handed out at those as well.

Q. So when you mention exhibit, are you suggesting -- there's a booth?

A. A booth, yes. So we probably do 40-plus smaller booths, you know, where there's a salesperson, a Boston Scientific display, and they're handing out these kind of brochures. We probably do between 40 and 60 of those a year, smaller ones.

Q. With respect to the national trade shows, you mentioned there's a large attendance. What do you mean by "large attendance"?

A. So the ATS and the CHEST meetings all are about 15 -- 10 to 15,000 in attendance from around the world. It depends on where the meeting is held. Attendance goes up and down, San Diego is a big draw, Denver not so big.

And then the allergy meetings, the AAAAI and the ACAAI, draw about 5 to 6,000 physicians, nurses, and respiratory therapists.

(Whereupon, Opposer Exhibit Number 4, Patient brochures titled A New Procedure for Severe Asthma, Bates BSC000558 through 700, was marked for identification.)

BY MR. WALZ:

Q. So you've been handed what's been marked as Deposition Exhibit Number 4.

A. Uh-huh.

Q. Do you recognize that exhibit?

A. I do. This is our patient brochure.

Q. And again, what's the approximate circulation of, or impressions made by this brochure?

MR. HANSEN: Object to foundation. Calls for speculation.

A. So the patient brochure -- so there's a few pieces here. So the patient brochure is like the first like 11 pages.

So this is a patient brochure that we developed at launch, so it was available to patients when we commercialized. This is the patient brochure that we give to physicians to hand to patients to explain the procedure. Through our website, if the patient wants more information, they would get this directly in the mail. This was done in conjunction with FDA, they approved this language, so it was an FDA-approved piece.

And since that time we've also created a second piece that's just slightly shorter and a little more concise. We found that this was almost too confusing or too much information for the patient, so we have a patient brochure as well as a patient pamphlet that conveys the core information. And we probably -- I know we've printed over 300,000 of these brochures since launch.

Again, they're given to the physician

offices, they're used at trade shows, they're used at these patient events. So it is our primary single thing that we use to educate patients, and always focused to drive them back to the website where they can get more information, they can log in and opt in to continue to receive more information.

Q. And you had mentioned there are about 300,000 of these that were printed you said?

A. The patient pamphlet and the patient brochure combined, the same two pieces, overall have been about 300,000.

Q. And how do you know that?

A. Based on purchase orders and what we've spent.

Q. And what has been the geographic reach of this particular brochure?

A. This particular brochure is worldwide, so it's used in -- you know, throughout the United States, we have over 350 centers today in the United States, we have another 100 centers outside the United States. This same brochure is used worldwide. We just translate it. But in Japan, China, Brazil, they're using the same exact brochure, but just translated.

Q. And for how many years has that brochure been used?

A. We've used this continually since we launched it in 2010.

I will say there was another version of this that had a picture of the -- it was actually branded for the AIR2 trial, so we used a very similar patient brochure to educate the patient on the procedure throughout our clinical study. And so the difference of that one was we had no results. So we were saying this is what the procedure will do, this is how it works, this is what your doctor is going to do, this is what you're going to do, but we didn't have any safety or efficacy data at that time. As soon as FDA approval and the trial was completed, then we were able to add results.

(Whereupon, Opposer Exhibit Number 5, Screen shots from Bronchial Thermoplasty website, Bates BSC000797, 812 and 813, was marked for identification.)

BY MR. WALZ:

Q. Now you've been handed deposition that's been marked Exhibit Number 5. Do you

recognize that exhibit?

A. Yes, this is screen shots from our website.

Q. What is the screen shot of?

A. So this is a portion of the website for patients, and it's basically -- on the website they would have clicked that they want more information, so there's support for patients or physician information. So if a patient entered their information, they're basically opting into our website database, and we would send them a DVD about the procedure, so it had animation, physician interview, patient interviews. So it was a multimedia way to educate patients.

Q. So when you refer to "it," you're referring to the DVD?

A. The DVD. If they clicked on this portion, they would get that patient DVD.

A lot of the information on the DVD is within the website itself, but sometimes people just want to have a DVD to review and don't want to just look at it only on-line.

Q. Now, how many DVDs have you distributed?

A. Well over 40,000.
Q. How do you know that?
A. Purchase orders.
Q. And what was the geographic reach of the DVD?
A. So again, that is across the United States, as well as globally. Our global partners in Europe, Asia, Latin America, Australia all have this same DVD. The same DVD is used in Australia and the UK directly. And our partners would have either translated or they dubbed, subtitled them to be in China. So they're still using the same DVD today around the world.
Q. You mentioned earlier that Boston Scientific made a television advertisement?
A. We did. We did the first TV ad, we found out, that Boston Scientific had ever done. We used patient testimonials, actual patients, those patients' videos appear on our website, and we used those video assets to create a very compelling, emotional, very strong TV commercial.
Q. And how many TV commercials has Boston Scientific produced?

A. We have produced the one for the Alair System, and that is the only one I'm aware of that Boston Scientific has released. There may be a second one that the neuromodulation group might have come out in the last year.

Q. What other marketing channels did the television ad lead to?

A. So we tested the TV commercial. It was a pilot in small markets, because media is very expensive, so we tested it, and we found that the call to action or the -- you know, with the phone number or the website on the TV commercial drove much more website traffic in that market than other markets where we were piloting different programs. So we saw that the television commercial definitely worked to drive more traffic. It was an expensive way to work. And it's also challenging, because unlike, you know, selling cars or tires, our market is very narrow, and so it's expensive to do television because you don't get to target to the asthma population.

So what we found was if we could use the emotional benefits of that TV commercial in a more targeted way, like if you could do a TV

commercial and only send it to asthma patients, that would be ideal.

So what we did was used that video, portions of that video, and did what we call rich media ads, and so they're digital advertising or banner ads that could be directed to sites where asthma patients would go to, like about asthma, or allergy websites, or different websites that we know that asthma patients tend to go to, and they'd see a banner ad, and when the mouse flicks over the banner ad, the video would start. And so the patient would get the benefit of the positive expense of the TV commercial and the much less expense for us.

(Whereupon, Opposer Exhibit Number 6, Bronchial Thermoplasty website pages, Bates BSC000814 through 821, was marked for identification.)

BY MR. WALZ:

Q. You've been handed what's been marked Deposition Exhibit Number 6.

A. Yep.

Q. Do you recognize that exhibit?

A. I do.

Q. And how do you recognize it?

A. So it's more of the btforasthma website for the Alair System. This is focused on the patient pages, or the patient portion of the website. [redacted]

And so we wanted to find a way to point out to patients that their life could be better. And so one way that we found is using a validated survey, it's called the Asthma Impact Survey, or the AIS-6, and this is -- this was created by allergists and pulmonologists and tested thoroughly and validated. So a very simple few questions that a patient answers, and based on their score it tells them how asthma impacts their life.

And so they may say their asthma is under control because they're taking medication, and they don't have attacks, but they never leave the couch, and they can't go to the park, and they can't do anything with their children.

And so this was a way to try to engage a patient to better understand their impact, the asthma impact of their life.

And so we put this on our website. We paid to a third-party company that owns the rights to this survey. And it's been very successful, because the patients who have taken this -- and we watched this, we can see it all digitally, we don't know by patients, we don't keep patient information, but we know patient numbers who have taken it, and over 75 percent of the people taking this impact survey have scored in the severe impact level.

So we feel very strongly that the patients that are coming to our website and reading this information and then taking this survey, asthma is impacting their life significantly.

And from this, they're able to actually print the results so that they have something to then bring in to their doctor and say, hey, I think asthma is really -- you know, my asthma is worse than I thought. And so the whole idea is to start the dialogue with their physician.

Q. What does that printout look like?

A. When you take the test and you hit "print," it literally prints a letter, and it has a beginning that says, you know, "Dear Doctor" -- you know, basically it kinds of leads into "asthma may be impacting my life more than I realize, and I'd like to talk with you about a new treatment for asthma."

Q. And what is that new treatment?

A. Bronchial thermoplasty delivered by the Alair System. I think the letter also has a couple key things about safety and efficacy about the Alair System in the head of the letter.

Again, because this patient may be taking this to their primary care physician who have not heard of the Alair System before, is not aware of a device for asthma, so this is one way to -- we like to educate the patient first -- or the physician first, and then when the patient goes to the physician the physician already knows about it, that's ideal, but it's very difficult to reach, you know, 100,000 primary care physicians. So this is one way to engage the patient more. So that's one.

The other is once they learn that asthma might really be impacting their life more than they thought, the next key thing is who is doing this in my area, who can I go talk to. So we have an interactive map on the website, and they can go and now pick by country, the 30 different countries, and they can click a country or state, and go and immediately pull up all of the physicians in their area that are offering this. So it gives the patient, if they don't already have a physician that they want to go talk to, it gives them other ideas of physicians who are doing the procedure, so that's -- the last page of this is the map, that's -- we call it the physician locator.

(Fire alarm interruption.)

BY MR. WALZ:

Q. So taking a look then at Exhibit 6, you talked about the success of the testing, but what are the quick statistics for this particular website, or web page?

MR. HANSEN: Objection. Calls for speculation.

A. So our web analytics from 2014, is the one that I remember most recently, was over

300,000 visitors to the website in 2014. We continue to monitor that every month. The data has been very consistent. Patients spend about a minute and a half on the website. We find that they go to how it works, and then find a clinic, are some of the most commonplaces where they go. We've got a wealth of data as far as how people flow through the website.

(Fire alarm interruption.)

(Whereupon, the reporter read back the above answer.)

BY MR. WALZ:

Q. Is there anything else you want to add to that before the buzzer went off?

A. No. I think the other pages you have here is the patient stories. We find that patients would often go to listen to what another patient -- a direct testimonial from patients, so that's another very popular place on the website for patients to learn how did other patients react to the procedure.

Q. And what has been the geographic reach of the website?

A. So it's global. Btforasthma is available around the world. We started with

focus in the United States. Again, we're in almost every state in the country as far as a clinic, this reaches clearly all 50 states. And then now it's international, so we've added -- this map now is no longer a U.S. map, it's a global map, and we've added a pull-down map by country, so there's over 30 countries that you could find a clinic.

And so this website will also soon be duplicated in multiple languages, so Spanish will be up very shortly to reach the Spanish-speaking population in the United States, as well as in Latin America and Europe, and then we'll also have Japanese, Chinese, Portuguese, French, Italian. So the exact same website will be duplicated in multiple languages.

Q. How many Spanish-speaking patients do you have, or customers do you have that request the Alair System?

A. I don't know numbers of Spanish-speaking patients. We have had requests since before FDA approval for the patient brochure in Spanish, and we do print that patient brochure in Spanish now. We've probably

printed 25,000 or more Spanish language brochures. But I think having the website in Spanish clearly will reach much more -- many more patients. We do have -- one of our patient testimonials also is up in Spanish.

(Whereupon, Opposer Exhibit Number 7, Printout of Bronchial Thermoplasty website pages, Bates BSC000825 through 833, was marked for identification.)

BY MR. WALZ:

Q. So now you've been handed what's been marked as Deposition Exhibit Number 7.

A. Mm-hmm.

Q. Do you recognize it?

A. I do. This is the physician portion of our website.

Q. And on the click statistics for this page as well, what are those statistics?

A. The how it works is still very key. Physicians want to know, you know, what is this about. We say it's for physicians. It's primarily for the referring physician. The physician who is treating or is interested in doing the procedure itself -- I always use my hands as a bronchoscope -- they've already

learned about the procedure from a sales rep most likely, or a peer-to-peer presentation, so this portion of it is really designed for the referring physician, the allergist and the primary care physician, to learn about the procedure so they can instruct the patients if this would be appropriate.

(Fire alarm interruption.)

A. So this is for physicians to really understand the procedure and the device, and to start to kind of uncover with the physician that their patients might have an option that they hadn't considered before.

BY MR. WALZ:

Q. And the click statistics for the patient portion of the website versus the physician portion of the website, do they differ?

A. I don't recall. And then this -- I will say that the last couple pages, this was a page that was added in 2013, and we had a logo for the five-year data, so this was a big push to get to the physicians to understand the five-year data. I believe we had a link directly to the publication. So that's when we

started to do a much bigger push through journal advertising to drive patients -- or to drive physicians, actually, to this portion of the website.

Q. So what press has the Alair System received?

A. We have had great press since actually before FDA approval. We've appeared on Good Morning America, the CBS Morning Show, Wall Street Journal, San Francisco Chronicle, New York Times. So again with the compelling patient story, that's really what we have used to try to get good press, so the stories always revolved around the patients, the revolutionary new procedure with the Alair system, and rarely did it actually mention the company name. It was a focus on the device and the patient.

Q. So did you mention -- you mentioned the Wall Street Journal. Did you mention the CBS --

A. CBS Morning Show, we had like a five-minute piece that was a patient interview, physician interview, and then there was a question and answer with the CBS resident physician and the anchor, and basically went

back and forth discussing the benefits of this new procedure, the Alair System.

Q. And when was that segment --

A. That was in --

Q. -- when it aired?

A. -- 2012, I believe. It's on our website. So a lot of those pieces of press, you know, newspaper articles, we've been on NPR, a great two-minute story on NPR, a lot of those we get approved by our legal and regulatory system, and then we can add them to the website.

In addition to that, we monitor different media hits, we'll call them, for the Alair System either on social media, on blogs, on TV, radio, newspaper, local newspapers. We have a search going on that every month, and I think in 2014 we had over 400 and -- over 400 different things appeared in the media about the Alair System and bronchial thermoplasty.

Q. So what is a media hit, can you describe that?

A. It could be an on-line blog, a TV news, the Channel 5 news in Boston would have a couple minute story about a local patient and a physician. When a new center gets started in

town, or the first center in a state, that was newsworthy often, so we'd get good coverage. We work with the local hospitals and their marketing departments to help get things placed. Newspaper articles, blogs, Twitter, Facebook, a lot of social media posts on the Alair System as well.

So some of those get put on our website. Many of those we can't get on our website because patients actually claim that they -- their results are so good that our data is actually not supportive of their results because they're so good. So we have a lot of great stories out there, but that are not necessarily all on our website.

Q. Okay. What sponsorships has Boston Scientific engaged in for the Alair System?

A. So we have sponsored a number of different -- with the professional societies we have sponsored, you know, trade shows and exhibits is one.

We've sponsored lunchtime symposia, product theaters, where they're sponsored by Boston Scientific and we pay to have a physician speaker at a trade show.

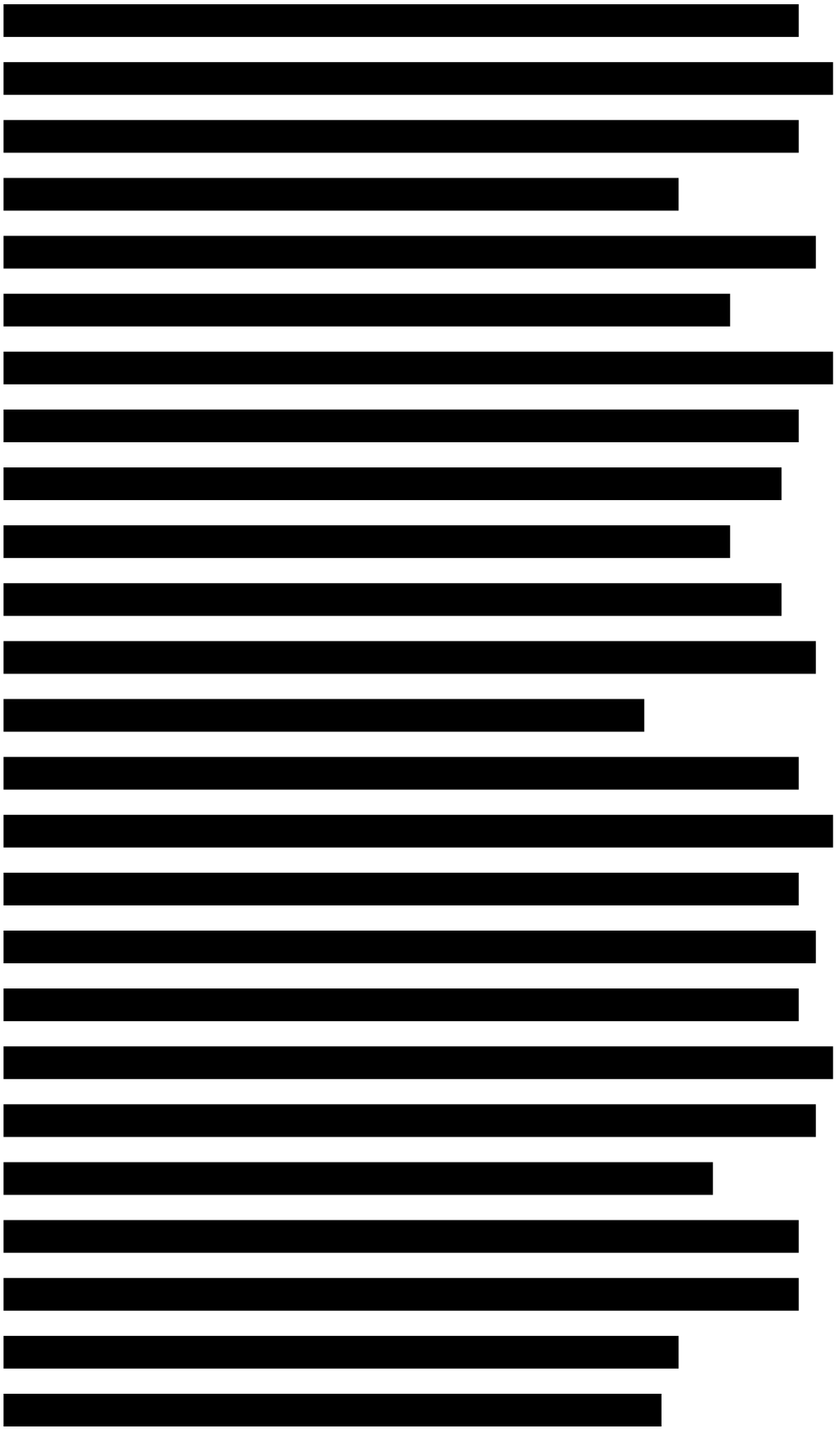
We've sponsored things through advocacy organizations, the Asthma and Allergy Foundation of America, or AAFA, is a very large patient advocacy group in the United States, they publish every year the asthma capital's report, and for two years we were the exclusive sponsor of that report. That generates a ton of press around the country. It comes out on World Asthma Day in May, May -- the first Tuesday in May, and so we've supported that organization.

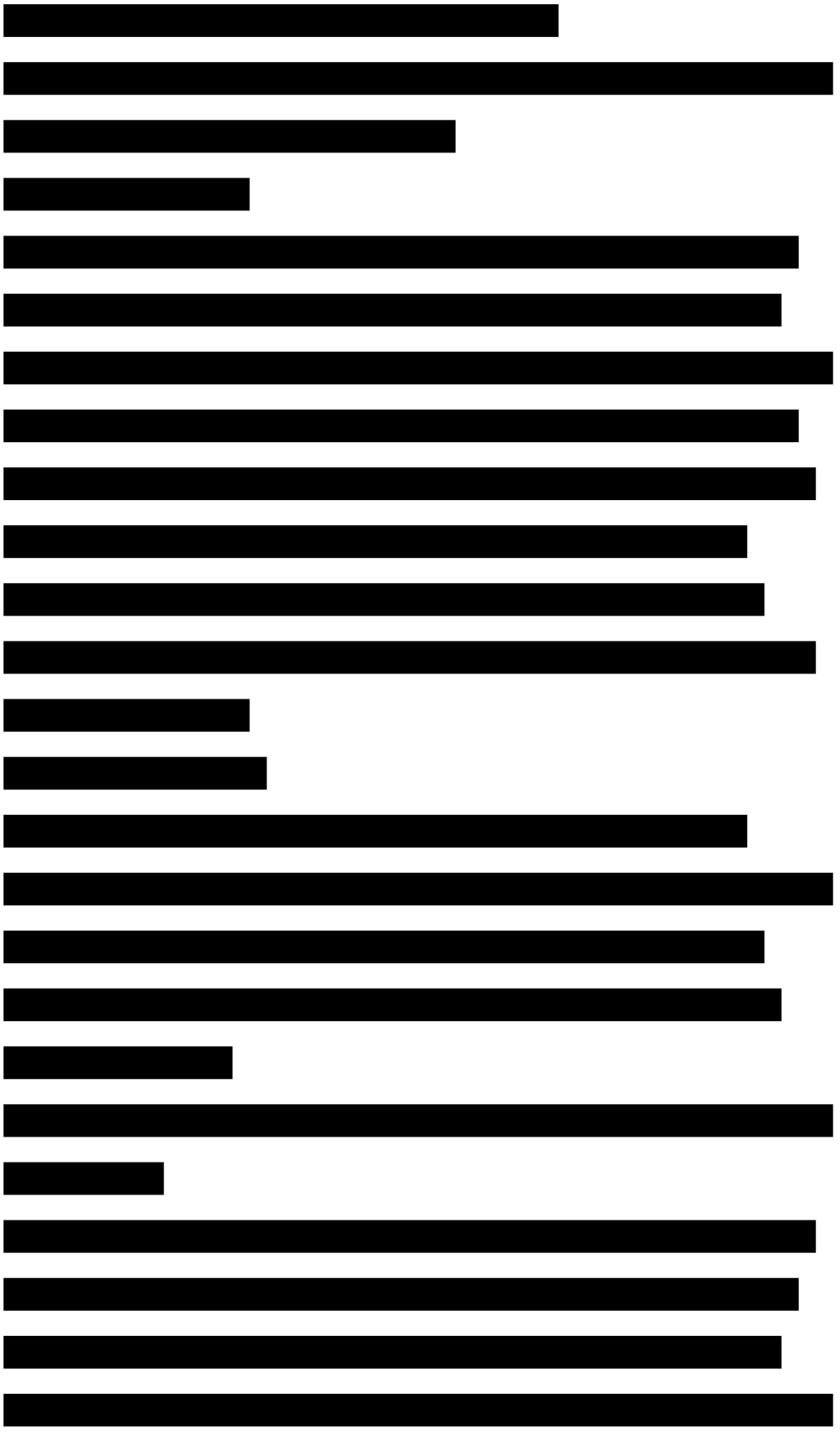
We've also supported the Asthma and Allergy Network, or AAN, another large patient advocacy group. They're very active in Capitol Hill. And we've supported that group as well for patient education, and working with both those organizations to improve patient access to the Alair System, and which is basically working through the insurance companies and getting insurance companies to cover the procedure.

And also the ALA, I think I mentioned that before, but we've sponsored probably over 50 different ALA activities around the country over the last few years, so those are ALA asthma walks, air climbs, different local events that the local ALA chapter will submit for

sponsorship to Boston Scientific.

[redacted]





[redacted]

BY MR. WALZ:

Q. Okay. I just want to make sure we're clear. I know we talked about this in the beginning, but in 2014, what consumer class were you targeting with the marketing expenses in 2014?

A. So in 2014, we're clearly going after the referring physician as well as the patient.

Q. Okay.

A. So it's all, you know, consumers, if you will, physicians, treating, referring, and patients.

Q. Okay.

MR. WALZ: I have no further questions.

MR. HANSEN: Shall we take a break, switch it up?

(Whereupon, a recess was taken from 10:13 a.m. to 10:21 a.m.)

CROSS EXAMINATION

BY MR. HANSEN:

Q. Ms. Passafaro, we met earlier, my name is Dennis Hansen, I represent Holaira in this matter.

A. Okay. Where are you based?

Q. I'm based in Minneapolis.

You understand that although we're not in a courtroom today, the testimony you're giving is under oath just as if you were in a court?

A. Yes.

Q. Okay. I'm going to hand you what's been marked as Applicant's Exhibit 1.

(Whereupon, Applicant Exhibit Number 1, Copy of trademark search, Bates BSC000119 through 453, was marked for identification.)

BY MR. HANSEN:

Q. Which is a copy of trademark search for the mark Alair performed in July of 2002 for the Fenwick & West firm in Palo Alto, California.

Do you see that?

A. Yes.

Q. This was produced by Boston Scientific in this case at BSC-119 through 453.

Have you seen this document before?

A. I have not.

Q. Okay. And you were not at Asthmatx --

A. No.

Q. -- at the time, correct?

A. I was not.

Q. You joined Asthmatx in 2005?

A. Correct.

Q. And in 2005, you joined as vice-president of marketing?

A. Vice-president of marketing.

Q. One of the kind of ground rules for a deposition is try not to talk over me, and I'll try not to talk over you. It makes it impossible for her to do her job.

And so in 2005 you joined Asthmatx as the vice-president of marketing?

A. Yes.

Q. And you testified earlier today that you have some awareness about the process that Asthmatx went through when deciding to obtain a trademark on the Alair name, correct?

A. Correct.

Q. And one of the things you mentioned that was done was a trademark search, correct?

A. Yes.

Q. And this is one of those trademark searches that was performed, correct?

A. I believe so.

Q. Okay. If you would, turn with me to Bates number BSC-163 in this document. The Bates numbers are these little --

A. Bottom right.

Q. -- bottom right numbers, correct.

A. 163?

Q. Yes, please.

On Page 163, there's a published trademark -- or a mark published for opposition at the time for Altair, an International Class 10, U.S. Class 26, 39 and 44.

Do you see that?

A. Mm-hmm.

Q. Do you know whether Asthmatx took any action related to this mark, this Altair mark when it decided to proceed with getting -- or attempting to get a trademark for Alair?

A. I was not at the company at that time.

Q. So nothing was done that you're aware of, correct?

A. Nothing that I was aware of in 2002.

Q. And nothing that you became aware of in 2005, correct?

A. In 2005?

Q. Right.

When you joined the company in 2005 --

A. I was not aware of anything, no.

Q. As you sit here today, you're not aware of anything?

A. I was aware of something with Altair after 2005.

Q. What are you were you aware of with respect to Altair after 2005?

A. The name had come up before FDA approval, around FDA approval, and I was asked about this name, and was not aware of an actual product that it represented, had not seen anything commercially with that name, was not

familiar with that product, with anything to do with pulmonology, asthma, allergy. It was a name that we were not aware of, or did not see represented in the marketplace.

Q. Okay. And so when did you become aware of it, do you remember?

A. Maybe 2009. There would have been -- I believe there would have been documents with our legal person who dealt with this. I was just consulted about the commercial viability or entity of Altair, what did I know about it commercially or competitively.

Q. In 2009, that was prior to the Boston Scientific acquisition?

A. Correct. This was -- I became aware of it at Asthmatx.

Q. Okay. And as far as you know, Asthmatx took no action with respect to the Altair mark?

MR. WALZ: Object as vague.

A. I'm not -- I don't believe we took -- I don't know what we did. I don't recall.

BY MR. HANSEN:

Q. Okay. Did --

A. Our legal people would have done that.

I was not involved.

Q. To the extent that there are records that reflect any action taken by the legal team with respect to the Altair name, you would expect that -- for example, if they sent a letter to Altair, you would expect those documents to exist, correct?

A. I would not be able to answer that, not being a part of the legal team.

Q. Okay. You don't know whether they preserve their records?

A. I do not know.

Q. Okay. Let's turn to BSC-180, please.

A. Mine is missing.

Q. Is that right?

A. Oh, it's back, it's double-sided.

Q. Sorry, it is a double-sided document.

A. The top half or bottom half?

Q. The bottom half referring to the Flair mark for International Class 10, U.S. Class 26, 39, 44 for "Medical Device; namely, a nebulizer."

Do you see that?

A. Mm-hmm.

Q. Do you know if Asthmatx took any

action with respect to the Flair mark?

MR. WALZ: Objection. It's hearsay.

A. I don't know.

BY MR. HANSEN:

Q. Do you know whether Boston Scientific took any action with respect to the Flair mark?

A. I don't know.

Q. Okay. Both the Altair mark and the Flair mark contain the three letters in sequential order A-I-R, correct?

A. Yes.

Q. Let's turn to BSC-184. BSC-184 has the mark Maxil-Air on it.

Do you see that?

A. Yes.

Q. And that's for a sinus ventilation tube, correct?

A. Yes.

Q. And that has the sequential letters A-I-R, correct?

A. Correct.

Q. Turn the page to 186. There's an entry here for Vitalaire.

Do you see that?

A. Yes.

Q. And that's "Medical Apparatus. Namely, oxygen concentrators for reducing air to a concentrated form of oxygen at home."

Do you see that?

A. Yes.

Q. And that also has the three letters in sequential order A-I-R?

A. Correct.

MR. WALZ: Objection. Vague.

BY MR. HANSEN:

Q. Well, in the word itself, Vitalaire -- do you see that -- there's the three letters A-I-R?

A. That's part of the word, yes.

Q. Correct. Okay.

If you turn the page to 187, there's Ventilair, which is a medical air compressor for respiratory therapy.

Do you see that?

A. Mm-hmm.

Q. And that also has the three letters in the name A-I-R, correct?

A. Correct.

Q. If you turn to 189, there is Circulaire, which is a "Medical Apparatus,

namely, aerosol products comprising delivery tubes, nebulizers, and reservoir bags for use in delivering pharmaceutical preparations in the form of inhalants."

Do you see that?

A. Yes.

Q. And that also contains A-I-R?

A. Yes.

Q. Let's turn to BSC-192. There's a mark here identified as Halayr.

Do you see that?

A. Mm-hmm.

Q. Are you familiar with that mark?

A. No.

Q. Are you aware that Novartis filed in 2013 for the Halayr mark for inhalers for medical purposes, medical apparatus for treating respiratory conditions?

MR. WALZ: Objection. Hearsay.

A. No.

BY MR. HANSEN:

Q. Are you aware that the United States Patent & Trademark Office published that mark for opposition on May 6, 2014?

A. No.

Q. Do you know whether Boston Scientific has taken any action with respect to the Halayr mark?

MR. WALZ: Objection. Vague.

A. No.

BY MR. HANSEN:

Q. And when I say "action," I mean any legal action.

A. I would not know.

Q. Okay. If we go to BSC-195, there is Cyclair, which is "Inhalers for administrating medications for use as an immunosuppressant, sold together as a unit with the medications."

Do you see that?

A. Yes.

Q. And that also has the three letters in sequential order A-I-R?

A. Yes.

Q. The next page, 196, has the mark Zolair, which is "Pharmaceutical preparations in the treatment of rhinitis."

Do you see that?

A. Mm-hmm. Yes.

Q. And that also has the three letters in sequential order A I -- Air, I'm sorry -- A-I-R?

A. Yes.
Q. Thank you.
The next page, 197, reflects the mark Eulair, E-U-L-A-I-R?
A. Yes.
Q. And that is for "Pharmaceutical preparations for the treatment of respiratory diseases," correct?
A. Yes.
Q. And it also contains A-I-R in sequential order?
A. Yes.
Q. The next page, 198, has a mark Zolayr.
Do you see that?
A. Yes.
Q. Which is for "Pharmaceutical preparations for the treatment of respiratory diseases, cardiovascular disorders, central nervous systems disorders, and for oncology and for use as an immunosuppressant"?
A. Yes.
Q. Broad?
A. Slightly.
Q. Okay. This doesn't contain the letters A-I-R, right?

A. No, it doesn't.

Q. But phonetically if you sound it out it's Zolayr as if -- phonetically it's the same as having A-I-R, correct?

A. Yes.

Q. If you go to Page 201, there's a mark Xolayr?

A. Yes.

Q. Did I pronounce that correctly?

A. I believe so.

Q. Is that a trade name you're familiar with?

A. This trade name, no.

Q. Okay. This is for "Pharmaceutical preparation for the treatment of allergic rhinitis and asthma."

Do you see that?

A. Yes.

Q. Is rhinitis related to asthma?

A. No. Rhinitis is a problem with allergies in the nasal area. Asthma can be allergic, but it's separate from rhinitis.

Q. And this, like the last one we looked at, ends in A-Y-R, correct?

A. Correct.

Q. Which is phonetically equivalent to A-I-R?

A. Correct.

Q. The next page, 202, is Singulair which is "Pharmaceutical preparations for the treatment of respiratory disorders."

Do you see that?

A. Correct.

Q. You're familiar with Singulair, correct?

A. Yes.

Q. Does Singulair treat asthma?

A. Not intended to, but it is used for asthma.

Q. Okay. And this ends in A-I-R, correct?

A. Correct.

Q. If you go to Page 236, there is Optimair.

Do you see that?

A. Yes.

Q. "Respirators other than for artificial respiration."

A. Yes.

Q. Correct?

This also ends in A-I-R, correct?

A. Yes.

Q. If we go to Page 248, there is Vitalaire.

Are you on the same page as me?

A. Yes.

Q. "Medical equipment rental services, namely, respirators, oxygen suppliers, ventilators, nebulizers and related breathing apparatus, therapy services, and retail respirators, oxygen suppliers, ventilators, nebulizers and related breathing apparatus store services."

A. Yes.

Q. And that also has A-I-R in it?

A. Yes.

Q. Would you agree with me that it's common to have the letters A-I-R or a phonetic equivalent in the trade name or trademark for a product or service that's designed to treat the respiratory pathways?

A. As you stated it, no. I see these product names as dealing with respirators, nebulizers, compressed air, not necessarily single use medical devices used in the

respiratory tract, or the respiratory airway. So I think these are -- they're slightly -- use of the word air with a respirator is different than what our product is, I believe.

Q. Sure.

I understand that therapeutically it's a different treatment, but all of these products are dealing with breathing, correct?

MR. WALZ: Objection. Speculation.

A. I would say no.

BY MR. HANSEN:

Q. Okay.

A. Just the liquid air, a nebulizer, they're dealing with different pieces of medical equipment. A ventilator, nebulizer, respiratory, they're dealing with different areas, so I wouldn't classify all of them as being -- dealing with the respiratory airway necessarily.

Q. Okay. And it's your testimony that it isn't common for the letters A-I-R or a phonetic equivalent to appear in the trade name or product name for products treating respiratory conditions?

MR. WALZ: Objection. Foundation.

A. I think air is used in different trademarks, whether it's respiratory or pharmaceutical or device, it's used in different areas different ways.

BY MR. HANSEN:

Q. And you would agree with me that it's certainly not uncommon for products or services dealing with respiration for A-I-R to be included as part of the name?

MR. WALZ: Objection. Foundation.

A. I would agree.

(Whereupon, Applicant Exhibit Number 2, Petition for Cancellation, Bates BSC000735 through 739, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed what's been marked as Applicant's Exhibit 2, which is a Petition for Cancellation, the Petitioner being Alere Medical Incorporated, the Respondent being Asthmatx, Incorporated. It was produced by Boston Scientific in this case at BSC-735 through 739.

Have you seen this document before?

A. I have not.

Q. This was not something you were involved in?

A. I was not.

Q. Okay. Do you recall that Alere sought to cancel the Alair mark?

A. I was aware of the trademark Alere. I was not aware of the actual action of a cancellation, that I was not familiar with. I was not involved in the legal action.

Q. Okay. And if you turn to Page 3 -- well, actually let's -- this will just be more expeditious if I mark another exhibit.

(Whereupon, Applicant Exhibit Number 3, Answer, Bates BSC000728 through 731, was marked for identification.)

BY MR. HANSEN:

Q. Applicant's Exhibit 3, just to identify it for the record, is the Answer by Asthmatx, Incorporated, the Respondent in the cancellation proceeding initiated through the petition identified in Exhibit 2. The Exhibit 3 was produced by Boston Scientific as BSC-728 through 731.

A. So this is -- Exhibit 3 is an answer to the activities of Exhibit 2?

Q. Correct.

A. Okay.

Q. And I understand you're not a lawyer, but I just have a couple basic questions regarding this.

So if you look at Exhibit 2, Paragraph 9, Alere Medical alleged that "The ALAIR mark that is the subject of Registration Nos. 2856168 and 3380080 is confusingly similar to Petitioner's mark ALAIR."

Do you see that?

A. Is that a typo? Because it says the Alair mark is similar to the Alair.

Q. Yes. I believe it is a typo, because they can't allege that Alair is confusingly similar to Alair, obviously.

A. But one of those is spelled wrong?

Q. Correct.

So Petitioner's mark would be the Alere mark.

A. So the second word in Alair at the end of the sentence should be A-L-E-R-E?

Q. Correct. I didn't draft it.

A. So I've never seen this before.

Q. And let's look at Paragraph 11 as

well, which says "Respondent's use of the mark ALAIR" --

A. That's the appropriate use of Alere word there?

Q. Correct.

"Respondent's use of the mark ALAIR for the goods and services identified" -- well, let me just --

A. Here it's Petitioner's corrected it?

Q. Asthmatx is the owner of the Alair mark at this time, correct?

A. Right.

Q. And Alair is identified as the Respondent, correct?

A. Correct.

Q. So when they refer to Respondent's mark, safe to assume that they're referring to the Alair mark; and when they're referring to petitioner's mark, safe to assume they're referring to the Alere mark?

A. Except in Paragraph 9.

Q. Right. That's obviously a typo.

Correct?

A. Correct.

Q. "Respondent's use of the mark ALAIR

for the good and services identified in Registration Nos. 2856168 and 3380080 is likely to cause confusion, mistake or deception as to the source of Respondent's goods and services, all to Petitioner's damage. Furthermore, customers or potential customers are likely to believe that Respondent's goods and services are sponsored or approved by or affiliated with Petitioner when that is not the case."

Do you see where it says that?

A. I see where it says that.

Q. If you turn to Exhibit 3, in Paragraphs 9 and 11 of the answer, Asthmatx denied the allegations of confusion that were contained in Paragraphs 9 and 11 of the Complaint.

Do you see that?

A. I see that.

Q. The basis of that denial was because Asthmatx believed that the Alair mark and Alere mark were sufficiently different as to not cause confusion?

A. I'm not aware of that reasoning.

Q. Not an unreasonable assumption that that would be the basis of a denial, correct?

MR. WALZ: Objection. Speculation.

A. I would not know.

BY MR. HANSEN:

Q. Who within Asthmatx was tasked with addressing legal matters such as the petition for cancellation?

A. That would be Nena Bains.

Q. Is she still with the company?

A. No.

Q. Where is she?

A. She is a partner at a law firm in the Bay area.

Q. And what is she always -- was she Asthmatx's employee at a time?

A. Yes. She left soon after the Boston Scientific acquisition.

(Whereupon, Applicant Exhibit Number 4, Alair Directions for Use, Bates BSC000662 through 675, and Number 5, Alair Operator's Manual, Bates BSC000677 through 692, were marked for identification.)

BY MR. HANSEN:

Q. You've been handed exhibits -- Applicant's Exhibits 4 and 5.

A. Yes.

Q. Which I'll identify for the record.

Exhibit 4 is the Alair Bronchial Thermoplasty Catheter Directions for Use produced at BSC-662 through 675.

Exhibit 5 is the Alair Bronchial Thermoplasty Radiofrequency Controller, Model ATS 200 Operator's Manual produced at BSC-677 through 692.

Are you familiar with Exhibits 4 and 5?

A. Yes.

Q. Are these documents that you or your team at Asthmatx or Boston Scientific created?

A. Yes. I created the originals with Asthmatx, and then was less involved in the final documents with Boston Scientific.

Q. These documents, Exhibits 4 and 5, they're provided to physicians who are going to be using the device, correct?

A. Yes, they are shipped with the product when the product is sold.

Q. Are they shipped with only the controller, or are they shipped with each catheter that's sold as well?

A. Exhibit 5 is shipped with each controller, which is a capital equipment single, so one operator's manual stays with the controller.

Exhibit 4 is shipped with each and every catheter.

Q. Does anybody else get these documents?

A. When asked, an operator's manual can be sent to purchasing or the service and maintenance within the hospital. If they wanted an extra copy, they could ask for one.

Q. Let's focus on Exhibit 4 to start.

A. The catheter directions for use, correct?

Q. Correct.

If you turn to Page 4 of that document, there's a section on the left-hand side that says "Warnings."

Do you see that?

A. Yes.

Q. And it indicates that "Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to the patient."

Do you see that?

A. Correct.
Q. That's a true statement, right?
A. Yes.
Q. If the device isn't used properly, it could harm a patient?
A. Correct.
Q. And it could cause serious harm to a patient if not used properly, right?
A. Yes.
Q. Boston Scientific requires physicians to be trained on how to use this device, correct?
A. Yes.
Q. And that's before they can use it in a live patient, correct?
A. Yes.
Q. And I believe when they're first starting out using the device with live patients, there's a Boston Scientific representative present, correct?
A. Typically, yes.
Q. And is that a Boston Scientific sales representative, or is that somebody else?
A. Sales, marketing, or clinical, someone appropriately skilled in the ability to proctor

cases.

Q. The Alair Catheter in the Alair System can't just be used by any physician, correct?

A. Correct.

Q. And, in fact, on the first page -- or Page 3 of this document, I guess, it says "For Professional Use Only. The Alair Catheter must be used by a physician who has training and experience in performing bronchoscopic procedures."

Do you see that? I'm sorry, I jumped ahead of you. So it's -- you're on the correct page, just right here (indicating).

A. "For Professional Use Only."

Q. "For Professional Use Only. The Alair Catheter must be used by a physician who has training and experience" --

A. -- "in bronchoscopic procedures," correct.

Q. And that's a limited subset of physicians, correct?

A. Yes.

Q. These are physicians who specialize in pulmonology, correct?

A. Correct.

Q. And they tend to be interventional pulmonologists, correct?

A. Not necessarily. A pulmonologist is trained in bronchoscopy. An interventional bronchoscopist or intervention pulmonologist is specialized in bronchoscopy, but all pulmonologists are trained to do bronchoscopy.

Q. Okay. It's more typical than not for a physician doing these type of procedures to be an interventional pulmonologist, correct?

A. No. The most common is just a pulmonologist.

Q. Okay. A pulmonologist trained in --

A. Trained in bronchoscopy, correct.

Q. And specifically trained in how to use this device?

A. Trained to use a bronchoscope, and then trained to use the Alair System.

Q. Okay. So there's two levels of training that go on, correct?

A. Correct.

Q. There's the standard training that a pulmonologist will have on how to use a bronchoscope, correct?

A. Correct.

Q. And then Boston Scientific will then provide training to the physician on how to use the Alair device?

A. The Alair System, correct. So it's training in bronchoscopy, and experience in bronchoscopy. So training, but then showing a consistent use of a bronchoscope and experience in bronchoscopy.

Q. Okay. And how do you assess the experience of a pulmonologist in -- I'm sorry, I'm bad at pronouncing this one.

A. Bronchoscopy.

Q. -- bronchoscopy?

A. That they routinely do bronchoscopy versus someone who was trained, did bronchoscopy in a fellowship and has not done a bronchoscopy for five years, that would not be someone experienced in bronchoscopy. They would need to do -- routinely do bronchoscopy every year.

Q. Okay. It's fair to say that the -- what I've seen referred to as the BT procedure --

A. Bronchial thermoplasty with the Alair System, correct.

Q. The BT procedure isn't for every

patient with asthma, correct?

A. Correct.

Q. It's for people with severe asthma, correct?

A. Correct, adults with severe asthma.

Q. And people with severe asthma who aren't being -- aren't becoming asymptomatic through the use of other medicines?

A. Correct.

Q. And the decision on whether somebody is a candidate for a BT procedure is an analysis done by one of the pulmonologists who is trained to perform the procedure, correct?

A. Yes.

Q. And obviously the patient is involved in the process, right?

A. Yes.

Q. They have to give their informed consent that, yes, they want this procedure, correct?

A. Yes.

Q. But the device itself can only be sold by a physician or on the order of a physician, correct?

A. It's sold to a hospital on the order

of a physician.

Q. Okay.

A. A physician would not buy the product.

Q. Okay. If we look at -- and we may be getting into semantics. But if we look at the very top of Page 3, it says "Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician," correct?

A. On the order of a physician would apply to a medical device, correct.

Q. Okay. And the typical process would be that the physician determines that a patient is a candidate for the procedure, correct?

A. Yes.

Q. He would then -- he or she would then get the consent of the patient to perform the procedure, correct?

A. Yes.

Q. Then he or she would notify the hospital purchasing office that they should place an order for an Alair Catheter?

A. Yes.

Q. And then the purchase would be made, correct?

A. Yes.

Q. What are the -- you talked about marketing channels, and what Boston Scientific does to market the product, and one of the things you mentioned was a direct sales force.

A. Mm-hmm.

Q. How many sales representatives does Boston Scientific have who are trained in to promote and sell the Asthmatx -- sorry, the Alair device?

THE WITNESS: Is that a confidential thing to share that as far as the scope of our sales force?

MR. WALZ: We'll designate pages as confidential, so you can answer.

A. This, I would think, should be kept confidential.

[redacted]

[redacted]

Q. Would you at least agree with me that the use of sales representatives is an important marketing effort?

A. Yes.

Q. The Page 3 identifies the indication for use for the Alair Bronchial Thermoplasty

System. It's on the right-hand side about halfway down. It says "The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled" -- can you help me with the --

A. Corticosteroids.

Q. -- "corticosteroids and long acting beta agonists," correct?

A. Correct. Hence, we say ICS and LABA.

Q. Got it.

It's not indicated for the treatment of COPD, correct?

A. Correct.

Q. And it's not marketed to treat COPD, correct?

A. Correct.

Q. Boston Scientific doesn't hold out to physicians that this product can be used to treat COPD, correct?

A. Correct.

Q. And Boston Scientific doesn't hold out to patients that this product can be used to treat COPD, correct?

A. Correct.

Q. You mentioned earlier that there were discussions regarding a potential clinical trial in the COPD space. Do you recall that testimony?

A. Correct.

Q. That clinical trial is not underway, correct?

A. By Boston Scientific, no.

Q. And is there even a clinical trial designed for use of the Alair System in treating COPD?

A. By Boston Scientific, not that I'm aware of. There may be independent investigator-sponsored research pursuing the use of the Alair product with patients with COPD.

Q. But not sponsored by Boston Scientific?

A. Not sponsored, at this point in time, no.

Q. What is Bronchus Technologies, Incorporated?

A. Bronchus was a company that was founded in the late '90s, a start-up medical device company focused in two areas; one was

emphysema, and one was asthma. Both products were under development under a single entity. And in around 2002, the decision was made by the board of Bronchus to split the companies in two; one company to pursue the emphysema product, another company to pursue the asthma product, the Alair System. So Asthmatx was spun out of Bronchus to pursue the asthma product with Alair. And Bronchus continued under that name to pursue the emphysema product, and I do not recall the trade name of that product.

MR. HANSEN: Okay. Let's go off the record for a moment.

(Off the record discussion.)

(Pause.)

BY MR. HANSEN:

Q. Just following up on the sales reps, their jobs are to have relationships with the doctors, correct?

A. That's part of their job.

Q. Right.

And as part of that relationship building, they hold themselves out as Boston Scientific representatives, right?

A. They represent Boston Scientific, yes.

Q. Right. I mean there should be no question in the physician's mind that this person is a representative of Boston Scientific?

A. Correct.

Q. And the representatives know which products Boston Scientific sells and which products they don't, correct?

A. I believe so.

Q. And you would expect that a Boston Scientific representative who has been promoting and selling the Alair device to be able to inform a physician that Boston Scientific doesn't sell the Alair device, correct?

A. I guess so.

(Whereupon, Applicant Exhibit Number 6, Screen shot of btforasthma website, Bates BSC000794, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Applicant's Exhibit 6, which is a screen shot of the website btforasthma.com produced at BSC-794 through 95. And you're familiar with --

A. This website, yes.

Q. Thank you.

The title of the website is Bronchial Thermoplasty, correct?

A. The title of the website is btforasthma.com. The Bronchial Thermoplasty logo is what is at the upper left corner of the website.

Q. Okay. Let's start with the URL. The domain or URL for this website is www.btforasthma.com?

A. Correct.

Q. Correct? That's the web address that somebody would type into their server --

A. Search, right.

Q. Sorry. Let's not -- let me finish my question.

That's the web address that somebody would type into their Internet Explorer to arrive at the website, correct?

A. Correct.

Q. Boston Scientific doesn't own Alair.com, correct?

A. I would not say no. I believe we may have purchased -- we purchased a number of different domain names that all redirect to btforasthma. I'm not familiar with what those

are. I know one, for example, is bronchialthermoplasty.com directs to btforasthma. At one point in time there was Asthmatx.com. I believe there was a variety of Alair URLs that also were in existence. I'm not familiar with what we have currently.

Q. Okay. If Boston Scientific owns Alair.com, that domain, you would expect that it redirects to this website?

A. Correct.

Q. And if they don't own it, it goes to some other business, correct?

A. Correct.

Q. At any rate, Boston Scientific has made the decision that the domain name, the main domain name for the page here, is btforasthma.com, correct?

A. Correct.

Q. And not Alair.com?

A. Correct.

Q. And if you look in the very far upper left-hand corner of this document, there's the words "Bronchial Thermoplasty," and then a little line, and then "Bronchial Thermoplasty."

Do you see that?

A. Correct.

Q. Do you understand that to be -- that the text "Bronchial Thermoplasty" is what appears in the browser tab on your internet browser when you're on this page?

A. Correct. It's a pull-down menu when you hit that. It's a browser tab with pull-down menu within it.

Q. I think we're talking about two different things. I just want to try to clarify this.

You're familiar with Internet Explorer?

A. Correct.

Q. And when you're on Internet Explorer, you can have multiple web pages open at once, correct?

A. Correct.

Q. And when you have a web page open, there's a tab at the top of your screen, correct?

A. Correct.

Q. And you can click on the different tabs to go to the different web pages you have open?

A. Yes.
Q. Correct?
And those tabs have text in them, correct?
A. Yes.
Q. To identify what web page is which?
A. Yes.
Q. And the text that appears for this web page in that tab is "Bronchial Thermoplasty," correct?
A. I'm unsure of that.
Q. Okay. The Bronchial Thermoplasty kind of logo directly beneath what we were just talking about, is that what you're saying is a drop-down menu?
A. Correct.
Q. And what appears at the drop-down?
A. So under the "Bronchial Thermoplasty," the first small letters, that would have "How It Works," the Alair System, it might have something about airway smooth muscle. I'm forgetting. And under "Real People, Real Results" you'd drop down and you'd see different patient video opportunities or physician interview. And "Are you a BT candidate," you

would see the quiz or the survey, and questions about who was the right candidate for BT. And then "Find a BT clinic," that pulls into the map.

Q. As we're looking at this -- this is the home page for the website, correct?

A. Correct.

Q. And as we're looking at this Exhibit 6, the only reference to Alair that I see is in this disclaimer towards the bottom of the page in small print that says Alair, and the Bronchial Thermoplasty logo "are registered trademarks of Boston Scientific Corporation." Correct?

A. On the home page, yes. And then when you click to, you know, how it works or the results, then you get into the Alair System.

Q. Okay. And on the home page, the only reference to Alair is in that disclaimer, correct?

A. Correct.

Can I provide more reason as to why? Okay. We're good. Yes.

(Whereupon, Applicant Exhibit Number 7, Screen shot of btforasthma website, Bates BSC000797 through 799, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Applicant's Exhibit 7, which was a document produced at BSC-797 through 799, and this is the "Support for patients" page on the btforasthma website, right?

A. Correct.

Q. You testified a little earlier about this DVD, correct?

A. Yes.

Q. And I presume copies of that DVD still exist, right?

A. Yes.

Q. And are you aware of whether any copies of that DVD were produced in this case?

A. I'm not aware.

Q. One way or the other?

A. I'm not aware one way or the other.

Q. Okay. As we're looking at this page, the only references to Alair are in the disclaimer, correct?

A. On this web page, yes.
Q. And I can't read the text on this DVD here all that well, but I don't see a reference to Alair on the DVD cover at least.
A. The trademark statement probably appears there.
Q. The disclaimer?
A. So it would say Alair, and the BT logo are trademarks of, I believe.
Q. Okay.
A. Below the BT logo in the center bottom of the DVD, I believe.
Q. This is a page that's -- the intent of this page is for patients or potential patients to access it?
A. For potential patients and their families or caregivers, yes.
Q. Okay. The text says "Start your BT journey."
Do you see that?
A. Yes.
Q. Does that refer to Bronchial Thermoplasty?
A. Yes.
Q. In the kind of banner at the top, it

says "BT. Because your world is bigger than your asthma."

Do you see that?

A. Correct.

Q. Again, that's a reference to Bronchial Thermoplasty?

A. Bronchial Thermoplasty, yes.

(Whereupon, Applicant Exhibit Number 8, Screen shot of btforasthma website, Bates BSC000803 through 805, was marked for identification.)

BY MR. HANSEN:

Q. Exhibit 8 is a document produced at BSC-803 to 805, it is the "Current treatment options" page of the btforasthma website, correct?

A. Yes.

Q. And this is a page that is intended to be accessed by potential patients and their families or caregivers?

A. Correct.

Q. This contains links to the Asthma Impact Survey that you referenced earlier, correct?

A. So when I referred to a drop-down

menu, the "Are you a BT candidate" at the top, when you click on that, this is your drop-down menu on the left, so you can go to "Take the survey," "Are you a candidate," "About asthma," and "Current treatment options." So this page, this Exhibit 8, is actually the pages of the last choice in the drop-down menu which is "Current treatment options." You would click on the "Take the Asthma Impact Survey" and that drop-down menu to take you to a different page.

Q. Okay. And that would lead you to the --

A. The survey.

Q. -- survey you discussed earlier, correct?

A. Yes.

Q. Underneath that it asks "Are you a BT candidate," correct?

A. And that's a separate -- that's a link, and that would bring you to a second page within this drop-down menu.

Q. It's asking or posing maybe the rhetorical question or maybe the very real question to the patient, their family or caregiver, are you a candidate for the BT

procedure?

A. Correct.

Q. And as I look through this page, I only see the reference to Alair in the disclaimer.

A. On this page, yes, because "Current treatment options" is describing other treatment options other than BT with the Alair System.

Q. So the answer is yes, it's only a disclaimer?

A. Yes.

(Whereupon, Applicant Exhibit Number 9, Screen shot of btforasthma website, Bates BSC000806 through 808, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Applicant's Exhibit 9, which was produced at BSC-806 through 808. This is the "About BT" page on the btforasthma.com website?

A. Yes.

Q. And this contains -- so this is -- using what you told me on the last exhibit, I think I'm learning here, so there's a line under "Bronchial Thermoplasty" with like a little

triangle?

A. Correct.

Q. That indicates that the drop-down menu for Bronchial Thermoplasty has been activated on this website, correct?

A. Correct. It's the four items on the left.

Q. "Proven benefits," "About Bronchial Thermoplasty," "Asthma and your airways," "How BT is performed"?

A. Correct.

Q. Okay. And Boston Scientific chose to include the link "About Bronchial Thermoplasty," correct?

A. Correct.

Q. Instead of saying about Alair, correct?

A. Yes, because we're explaining what Bronchial Thermoplasty is in this drop-down menu. Inserting Alair there would have been confusing.

Q. And you made the choice to say "About Bronchial Thermoplasty," correct?

A. Correct.

Q. And you gave the reasons for your

choice.

On this page there's the use of Alair in the disclaimer, and the use of Alair one other time on the page?

A. "BT delivered by the Alair System."

Q. And those are the only two references to Alair, correct?

A. Correct, on this page. But the "Learn about how BT performed" is a link that will take you to describing the Alair System.

Q. I'm only talking about this page right now.

So on this page, those are the only two references to the Alair mark, correct?

A. Yes.

(Whereupon, Applicant Exhibit Number 10, Screen shot of btforasthma website, Bates BSC000812 and 813, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Exhibit 10, which is a document produced by Boston Scientific at BSC-812 through 813, this is the "Are you a BT candidate" page on the btforasthma.com website, correct?

A. Yes.

Q. And the four clickable links, "Asthma Impact Survey," "Are you a BT candidate," "About asthma," "Current treatment options" are the drop-down on this page, correct?

A. Yes.

Q. The Alair name is only used in the disclaimer of this page, correct?

A. Yes.

Q. Under the -- in the text on the second page, on 813, there's a question posed, "Who performs the BT procedure?"

Do you see where I'm at?

A. Mm-hmm.

Q. It says "BT is performed by a specialty trained pulmonologist."

Do you see that?

A. Yes.

Q. And we talked briefly about that training before, correct?

A. Yes.

Q. And it indicates "If your regular doctor currently managing your asthma is an allergist, family practice physician, general practitioner, internist or other physician, he

or she will be able to refer you to a BT clinic for a consultation with a pulmonologist."

Do you see that?

A. Yes.

Q. And these types of physicians identified, those are the types of referring physicians --

A. Yes.

Q. -- that we've talked about, correct?

A. Yes.

Q. BT clinic, that refers to a clinic that has one or more physicians at it that have been trained to use the Alair System?

A. Correct.

Q. Okay. And Boston Scientific has made the decision to call those BT clinics, correct?

A. Correct.

Q. Instead of Alair clinics, correct?

A. Correct.

Q. And if I'm reading this correctly, I mean this is kind of a -- this sentence kind of describes to the patient the basic process that should be followed; if your regular asthma doc isn't a pulmonologist, they can refer you to a doctor who is who can consult with you on

whether you're actually a candidate or not for BT, correct?

A. Yes.

Q. And that would be kind of a typical process followed by a patient, correct?

A. Yes.

Q. And kind of every step of the way they're being consulted by a physician, correct?

A. Yes.

Q. And when the ultimate decision is made on whether to have this procedure performed, to use the Alair device, that's in consultation with a doctor who is specially trained to use the Alair device, correct?

A. Correct, the doctor and the patient together.

Q. Correct. Okay.

(Whereupon, Applicant Exhibit Number 11, Screen shot of btforasthma website, Bates BSC000814 through 816, was marked for identification.)

BY MR. HANSEN:

Q. Exhibit 11 is a document produced by Boston Scientific at BSC-814 through 816, and this is the page that contains the Asthma Impact

Survey on the btforasthma.com website, correct?

A. Yes.

Q. Earlier you testified regarding about kind of what the -- how the result of the impact survey is conveyed to the potential patient, correct?

A. Yes.

Q. Are you aware of whether or not any exemplars of how that's conveyed were produced in this case?

A. I'm not aware.

Q. You're just not aware one way or the other?

A. No.

Q. This page contains one reference to Alair in the text, and then one reference in the disclaimer, correct?

A. Correct.

(Whereupon, Applicant Exhibit Number 12, Screen shot of btforasthma website, Bates BSC000817 and 818, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Exhibit 12, which is a document produced at BSC-817 to 818. This

is the "Find a BT Clinic" portion of the btforasthma.com website, correct?

A. Yes.

Q. And the Alair name is only used in the disclaimer on this page, correct?

A. Yes.

(Whereupon, Applicant Exhibit Number 13, Screen shot of btforasthma website, Bates BSC000819 through 821, was marked for identification.)

BY MR. HANSEN:

Q. You've been handed Exhibit 13, which is a document produced at BSC-819 through 821, and this is the "Patient stories" portion of the btforasthma.com website, correct?

A. Yes.

Q. This is the portion that you, I think, testified earlier where people can access the patient testimonials?

A. Yes.

Q. And these -- the testimonials here are what were used for the television commercial?

A. Portions of these, yes.

Q. Okay. Were there any other patient testimonials used, or portions of patient

testimonials used for that television commercial?

A. No, they would have come out of this subset.

Q. Okay. On this page there's one reference to Alair in the text, and then the standard reference to it in the disclaimer, correct?

A. Correct.

Q. And if we -- we can review all of the videos if you want, I have them, but just to shortcut it, hopefully you have a memory, the only reference to Alair in these videos is in a disclaimer at the very end of the video, correct?

A. I believe so, correct.

Q. The patients in the videos when they're giving their testimonials refer to it as BT?

A. Yes.

(Whereupon, Applicant Exhibit Number 14, Screen shot of btforasthma website, Bates BSC000822 through 824, was marked for identification.)

BY MR. HANSEN:

Q. Before we turn to the next exhibit, a question about the television commercial. What market was that run?

A. Dayton, Ohio.

Q. Is that the only market?

A. Yes.

Q. When was that television commercial run?

A. I believe it was 2013, middle of the year 2013.

Q. Do you know for how long of a period of time it was on the airwaves?

A. I believe about 12 weeks. It was a pilot, so it was a defined period of time.

Q. Was there -- how many channels did it air on?

A. It aired on a variety of channels. We bought media through a media broker, if you will, so we bought air time at certain times and certain channels and networks that our research showed that patients in our age demographics were most likely to see the commercial.

Q. Who was the media broker?

A. Our agency was Giant, an ad agency out of San Francisco, and they handled the brokering

for us. I believe they went with a third party, and I don't remember that name.

Q. Do you know whether that television commercial was produced in this case?

A. Produced?

Q. Produced to Holaira in discovery.

A. I don't know.

Q. Okay. You just don't know one way or the other?

A. I don't know one way or the other.

Q. Do you know whether any documents that would reflect the placement of the television ad on various channels at various times, do you know whether any such documents are maintained by Boston Scientific or its advertising agency?

A. I believe there would be documentation with the ad agency.

Q. Do you know whether any of that was produced in this case?

A. I'm not aware.

Q. Do you have -- well, never mind. I'll move on to this next exhibit, which I believe is Exhibit 14.

Exhibit 14, BSC-822 through 824, which is the "Physician stories" portion of the

website, correct?

A. Correct.

Q. And this page has one use of Alair in the text, and it has the standard use in the disclaimer, correct?

A. Correct.

Q. And similar to the patient videos, these videos refer to BT as opposed to Alair, correct?

A. I'm not sure. I would believe that with the physician videos, there's more of a discussion about the Alair System since the physicians are describing the procedure in more detail to a patient. So the quote on this page may only refer to BT, but in the body of the video, I believe a number of them refer to the Alair System.

Q. Okay. And let's just bypass it by doing this. I mean I can show you the videos. But you would agree the videos are what they are, right?

A. Yes.

Q. And what was produced in this case should be a true and accurate copy of the videos that are available on the website, correct?

A. I would assume so.
Q. Okay. You have no reason to doubt that true and accurate copies weren't produced in this case?
A. No.
Q. And your testimony regarding the use of Alair within these videos seemed a little bit equivocal, you may have been guessing based on your memory?
A. I don't have absolute certainty that Alair is in there. I'm assuming it is mentioned by a physician, yes.
Q. But you would defer to the video?
A. Yes.
Q. If it's not actually in there, you wouldn't dispute what the video says?
A. Yes.
Q. Okay. Let's just leave it at that.
A. Cut to the chase.
Q. Let's leave it at that instead of playing all the videos and having recess time watching movies.
A. Thank you.
Q. Let's move on.

(Whereupon, Applicant Exhibit Number 15, Screen shot of btforasthma website, Bates BSC000825 through 827, was marked for identification.)

BY MR. HANSEN:

Q. Exhibit 15 has been handed to you, which is document produced by Boston Scientific at BSC-825 through 827, and this is the "Overview for Physicians" page of the btforasthma.com website, correct?

A. Correct.

Q. And this is -- I think you testified previously that this is intended for referring physicians to educate themselves on the device and procedure, correct?

A. Yes. Referring and treating, primarily referring.

Q. Okay. There are four total uses of Alair on this page that I could find, three in the text, one in the disclaimer.

A. I believe that's true. Yes.

Q. And on the second page, on 82 --

A. Well, four, because there's -- on one of the drop-down menus at the top is the Alair System, that's literally on this page, and then

in the text there's three, and then a fourth in the disclaimer.

Q. Got it. Thank you.

On the second page, 826, there's a section "Who performs the BT procedure?"

Do you see that?

A. Yes.

Q. And it says "BT training is required, and includes: Review of the Alair System Catheter Directions and Use and Controller Operator's Manual," right?

A. Yes.

Q. "Guided didactic instruction in computer simulation-based Bronchial Thermoplasty Learning Center."

Do you see that?

A. Yes.

Q. And that's the computer training that you referenced earlier?

A. Yes.

Q. "Detailed in-service training of the Alair System."

Do you see that?

A. Yes.

Q. And that is performed by who, that

training?

A. A Boston Scientific sales rep.

Q. Okay. And then "Hands-on training with Alair System in a lung model prior to initial cases."

Do you see that?

A. Yes.

Q. And who does that?

A. A Boston Scientific representative.

Q. Okay. Is working with the physician to complete that training?

A. Correct.

Q. "Proctoring of initial cases by Boston Scientific Health Care Industry Representative."

Do you see that?

A. Yes.

Q. Is a health care industry representative the same as a sales rep?

A. Yes.

Q. And then "Ongoing support of cases when requested."

Do you see that?

A. Yes.

Q. And that is if a physician has a request to have any kind of support for a

procedure, Boston Scientific will provide it?

A. Yes.

Q. Any kind of question on if they have a particularly difficult patient or problem with the device, they can call Boston Scientific and get support?

A. Yes.

Q. Is there any other training that isn't listed here?

A. No. There's actually four instances of Alair in the text; one in the drop-down menu, and then another in the disclaimer, so there would be six total.

Q. Six total on this page?

And the hope in providing this training is that once the training is complete, that the doctor is familiar with the device, right?

A. Correct.

Q. And is able to competently use the device?

A. Correct.

Q. So that no mistakes are made in the procedure, correct?

A. Correct.

Q. And you would expect that a doctor who encounters an issue with a device to notify Boston Scientific, correct?

A. Yes.

Q. If they open a box and say "this looks a little bit different from what I've received in the past," you would expect them to contact Boston Scientific and inquire about that?

A. Yes.

(Whereupon, Applicant Exhibit Number 16, Screen shot for btforasthma website, Bates BSC000828 and 829, was marked for identification.)

BY MR. HANSEN:

Q. Exhibit 16 was produced by Boston Scientific at BSC-828 through 829. This is the "Physician information request" page on btforasthma.com, correct?

A. Yes.

Q. And is this intended for physician use, or for potential patient use?

A. This exact page you would get to by clicking the "Physician information request" and it brings you to this page. There's a separate page for patient information.

Q. Okay. So this would be -- doctors use this?

A. Doctors.

Q. The only reference to Alair on this page is in the disclaimer, correct?

A. Correct.

Q. Earlier you testified about data relating to clicks onto the website, website traffic, correct?

A. Correct.

Q. Is that data that Boston Scientific regularly keeps and tracks?

A. Yes.

Q. Do you know whether any of that information was produced in this case?

A. I'm not aware.

Q. Just don't know one way or the other?

A. Don't know one way or the other.

Q. Were you involved at all in the effort to collect documents to produce in this case?

A. Yes.

Q. Did anybody ask you to provide such documents, the click, or the web traffic documents?

A. I'm not aware one way or the other.

Q. Okay. Is there anybody else in -- well, is it part of your job to track the web traffic?

A. It's someone on my team.

Q. Okay. Who is that?

A. It would be Bri Amarillas.

Q. And Bri reports up to you?

A. Into another manager, and then to me.

MR. WALZ: Do you want to break for lunch at some point?

MR. HANSEN: Sure. Let's go off the record.

(Off the record discussion.)

(Whereupon, Applicant Exhibit Number 17, Brochure titled A New Procedure for Severe Asthma, Bates BSC000558 through 569, was marked for identification.)

BY MR. HANSEN:

Q. I've handed you Exhibit 17, which is BSC-558 through 569.

A. Yes.

Q. I believe this was included in a compilation exhibit that you looked at earlier today?

A. Yes.
Q. You identified this as a brochure that's provided to potential patients?
A. Yes.
Q. Is that correct?
On Page 9, BSC-566, there is a description of the BT procedure, correct?
A. Correct.
Q. And is that -- is every BT procedure done in three treatments like is described on this page?
A. Yes.
Q. This is kind of the standard way to do it, correct?
A. Yes.
Q. Is there anything that's inaccurate about this page in terms of how the procedure is generally performed?
A. No, this is correct.
Q. Okay. And if we go to Page 11, there's a section that says "What happens after each BT treatment?"
A. Yes.
Q. And that's -- there's three treatments, and this is what is done in-between

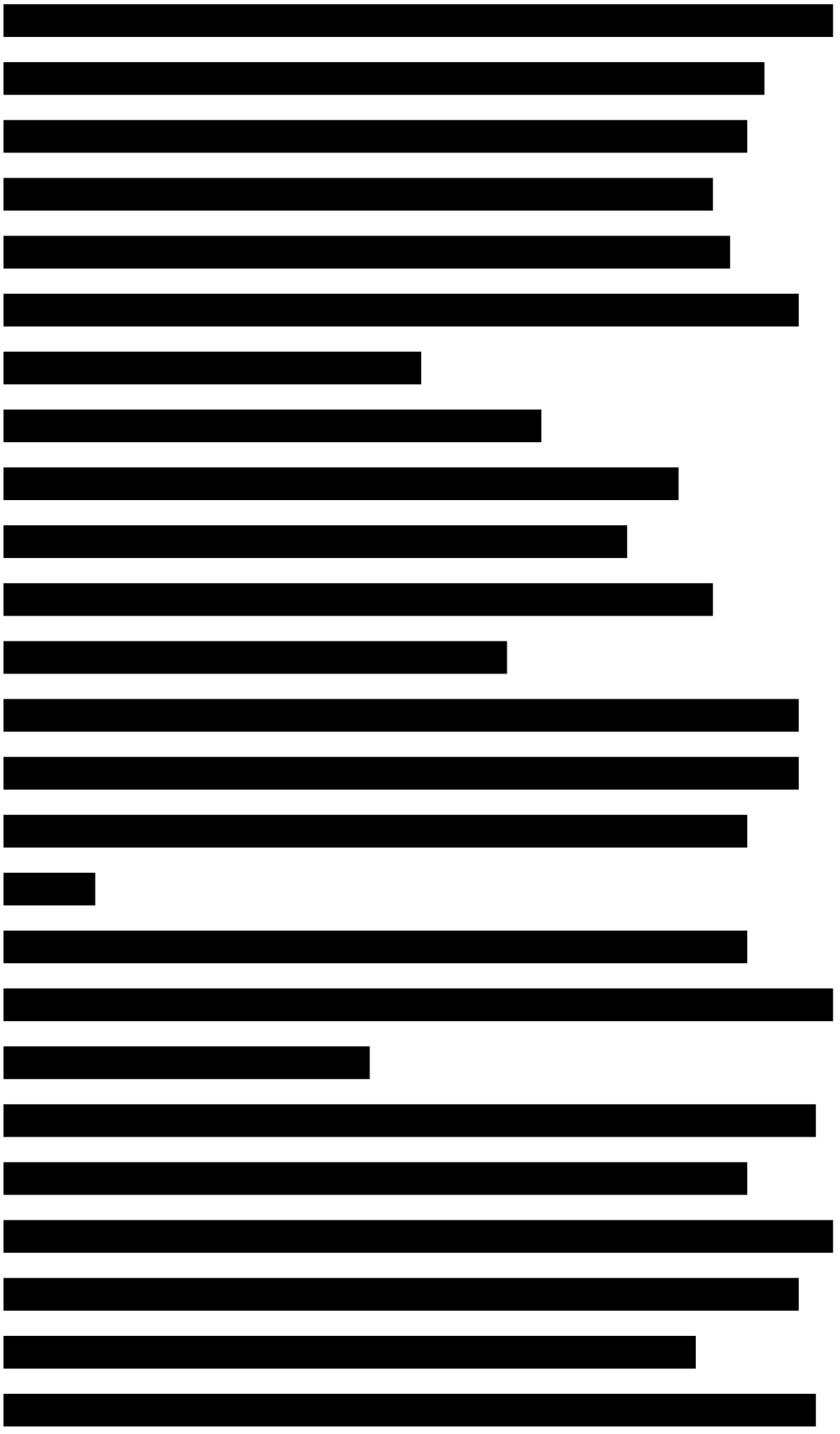
those three treatments, or just after each treatment, correct?

A. After each treatment, correct.

Q. And is there -- this is all accurate, correct?

A. Correct.

Q. [redacted]



[redacted]

Q. Okay. You testified that there was PR in a variety of channels, right?

A. Yes.

Q. New York Times, San Francisco Chronicle, and a variety of different, I think what you called, quote unquote, media hits?

A. Correct.

Q. Are all of these, quote unquote, media hits maintained by Boston Scientific? Do you have copies of all of them?

A. We have copies of some. Others we don't have copies because they're copyrighted by CBS or the New York Times. For some we purchased copyright ability so we could do a reprint.

Q. So for ones that are copyrighted by, say, the New York Times, you don't have a clipping out of the newspaper at the office that reflects the actual article that it was referencing?

A. We probably saved a copy, but that's not something that we own and can distribute.

Q. Right.

You don't publicly redistribute it?

A. No.

Q. I'm just asking if you have a copy of these things, whether or not you redistribute them or not.

A. I believe I have a copy.

Q. Okay.

A. Some of them are internet links.

Q. Right. So you might have a link to a video on the internet that reflects a news story that occurred in the past?

A. Right. Or linked to CBS News, and within that.

Q. Got it.

You mentioned a banner ad, I think you called it rich digital, which is a video that is kind of streaming when you scroll over the

banner ad?

A. Correct.

Q. Do you know whether that video has been produced in this case?

A. I'm not aware.

Q. And that video was created using portions of the patient testimonials?

A. Correct.

Q. You testified regarding trade shows that Boston Scientific regularly attends for the Alair device.

A. Correct.

Q. Right?

A. Yes.

Q. And you said that 10 to 15,000 folks attend the -- I think what you identified as the CHEST and the ATS --

A. Yes.

Q. -- trade shows?

Okay. And those 10 to 15,000 people, those are medical care -- medical professionals, correct?

A. Correct.

Q. Okay.

(Whereupon, Applicant Exhibit Number 18, PowerPoint titled Asthmatx, Bates BSC000623 through 643, was marked for identification.)

BY MR. HANSEN:

Q. I've handed you Exhibit 18, but before we start discussing it, are you familiar with the term Class 3 medical device?

A. Yes.

Q. And that's an FDA designation, correct?

A. Yes.

Q. The Alair System is a Class 3 medical device, correct?

A. Yes.

Q. And the FDA restricts how Class 3 medical devices can be marketed and sold, correct?

A. Correct. I believe that Class 3 also implies the approval process.

Q. Right. Class 3 medical devices have to go through a different approval process than Class 2 or Class 1?

A. More rigorous, yes.

Q. And that's -- it requires, in most

cases, a randomized trial, correct?

A. Yes.

[redacted]

[redacted]

Q. What competition was Asthmatx

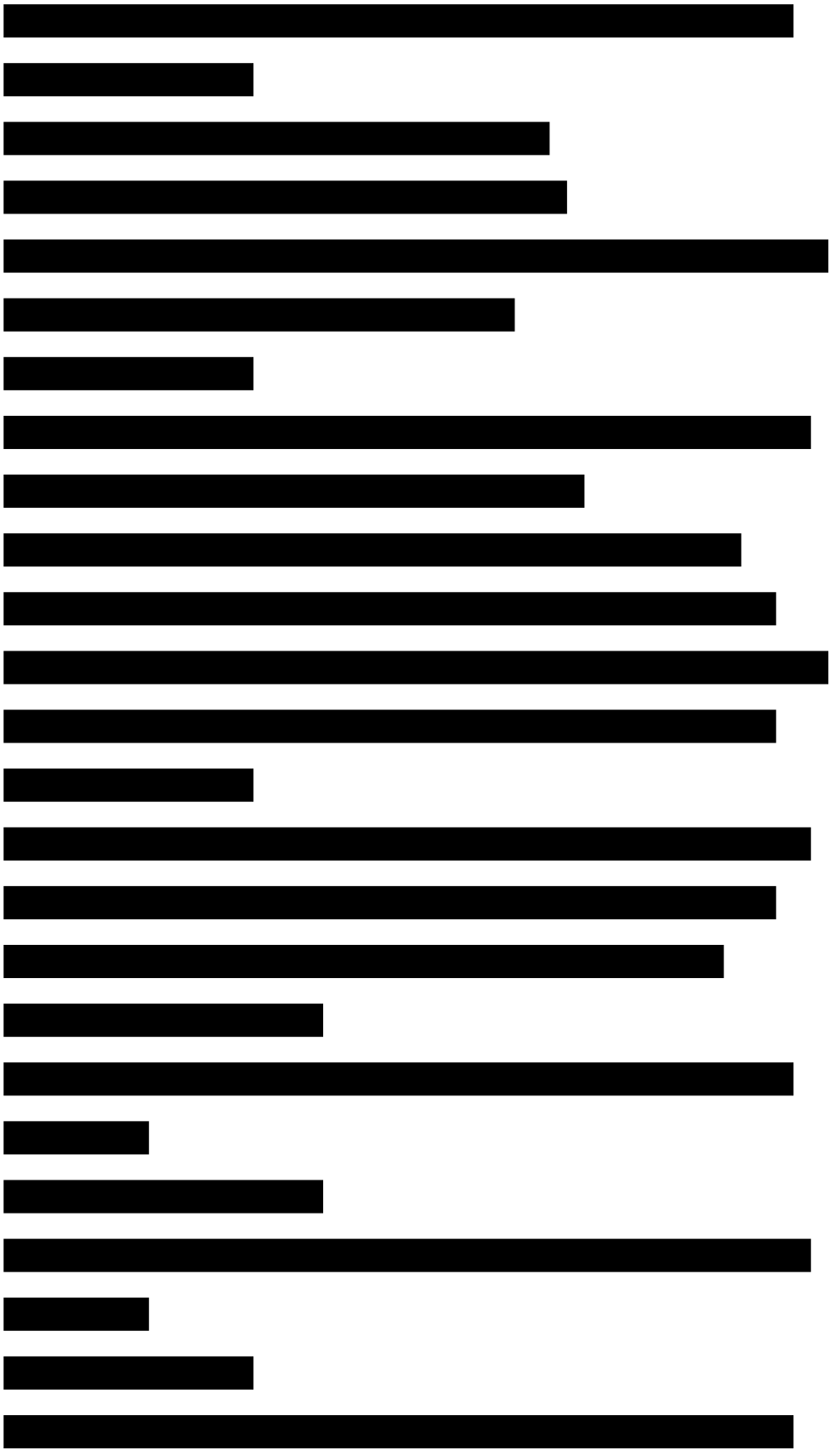
anticipating, if any, at this time in 2009?

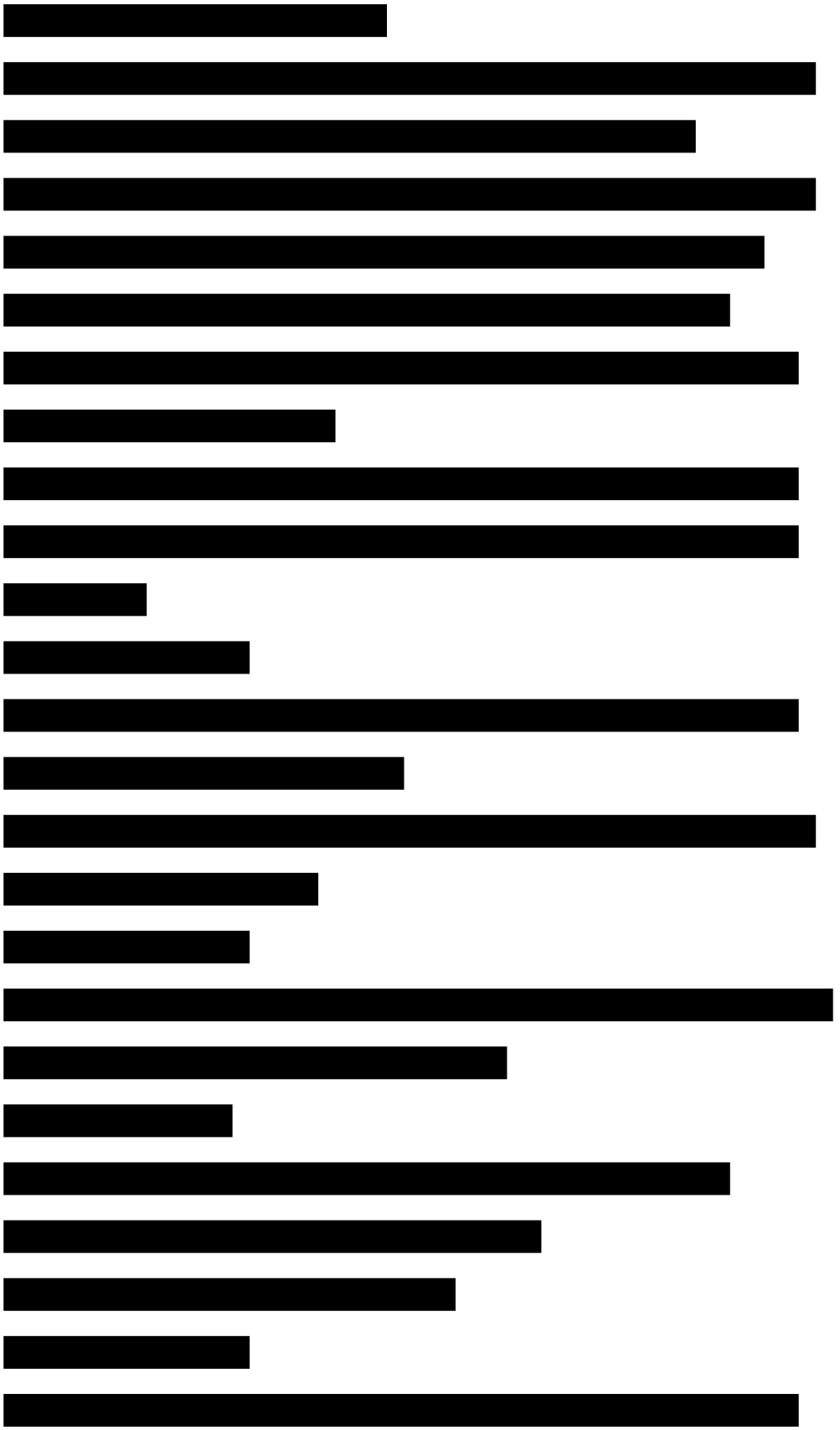
A. In 2009, there were no direct competitors for the device for asthma, but this was looking -- you know, this was a project should there be competitors enter the market, this is why we retained them.

Q. There were no specific competitors in the market at this time?

A. At this time, that we were aware of.

[redacted]





[redacted]

Q. The website and how it appears, has it been consistent roughly since 2009?

A. So it went live commercially in 2010. It's been fairly consistent, yes.

Q. Okay.

A. In 2010, there was the Bronchial Thermoplasty web page, there was a separate Asthmatx web page that was a corporate type, not product-related, and that website subsequently went away. And the Bronchial Thermoplasty page designed for patients has continued in roughly the similar focus, it's changed over the years

graphically and function-wise, but the basic premise has been the same.

Q. With respect to the trade shows that you've attended, or maybe not you personally, but Asthmatx/Boston Scientific to promote the Alair device, Holaira representatives have been at those same trade shows, correct?

A. No.

Q. Never?

A. They have not exhibited, that I'm aware of, at any trade show. They had a presence, I would say, not commercial presence, but a podium presence at the European Respiratory meeting in 2014, September of 2014.

Q. And when you say "podium presence," they gave a presentation?

A. It was a sponsored presentation paid for by Holaira during the European Respiratory Society meeting.

Q. Okay. And is that the -- earlier you provided testimony on how the Holaira system works, and you said that you saw a presentation. Is that where you saw the presentation?

A. This was the presentation, correct.

Q. Okay.

A. September, 2014.

Q. Let me just flip through my notes real quick, and I may be done.

With respect to print media --

A. Yes.

Q. -- where has the print media been placed?

A. So as far as paid advertising?

Q. Correct.

A. We've done a number of advertisements that included editorial additions in inserts in the USA Today that appeared in the -- one in the DC market, one in the Chicago market, one in the LA market. That was part of the USA Today.

We also did BT -- or we did Bronchial Thermoplasty Alair System ads in Houston for a pilot. Again, that was at the same time we did the television commercial. We had newspaper ads running in Houston.

And there's been a number of newspaper ads that have been done by the hospitals that Boston Scientific has not funded, but we're aware of many different local advertisements done by the hospitals.

Q. Do you have copies of those

advertisements?

A. I have copies of some of them.

Q. Do you have copies of the advertisements that Boston Scientific has run?

A. We have copies within the office, yes.

Q. And do you have records that reflect where and when those were run?

A. I believe so, yes.

MR. HANSEN: I don't believe I have any further questions for you at this time. Thank you.

A. Thank you.

MR. WALZ: Do you want to break for lunch and then we'll come back?

(Whereupon, a luncheon recess was taken at 12:30 p.m.)

AFTERNOON SESSION

REDIRECT EXAMINATION

BY MR. WALZ:

Q. So we're back, now we're going to finish up with the redirect, having Dennis finished with his cross-examination.

Can you take a look at Applicant's Exhibit Number 1?

A. Okay.

Q. So you were first asked to look at page Bates numbered BSC000163.

A. Okay.

Q. Are you familiar with the applicant, Hitachi Medical Corporation?

A. No.

Q. You'll see here under "Additional Info," it says "Filed as an intent to use"?

A. Mm-hmm.

Q. Do you have an understanding of what that means?

A. I would assume that they're filing for the trademark before they're able or ready to actually use that for a product.

MR. HANSEN: Object as speculation.

BY MR. WALZ:

Q. And if we look underneath the "Goods and Services" heading, it says "MRI Diagnostic Apparatus and Parts Thereof"?

A. Mm-hmm.

Q. Does an MRI diagnostic apparatus compete with the Alair System?

A. No.

Q. Would the MRI diagnostic apparatus be marketed in the same channels as the Alair System?

A. No.

Q. If you could look at BSC000180. So that's the record you were asked to look at for the mark Flair?

A. Flair, yes.

Q. Are you familiar with the Correspondent listed, Monte R. Browder?

A. No.

Q. I'm sorry, that was the wrong, I meant the Applicant, IVAX Research, Inc.?

A. No.

Q. Do you see under "Additional Information" it's -- the heading, or it's stated "Filed as intent to use"?

A. Yes.

Q. Do you understand what that means?

MR. HANSEN: Object to foundation.

A. It's not in use.

BY MR. WALZ:

Q. So you previously testified that you are the vice-president of marketing?

A. Correct.

Q. And part of your job duties is to work with counsel on clearing trademarks and filing trademark applications?

MR. HANSEN: Object to form. Leading.

A. I would be consulted by the legal team when they were doing trademark work, yes.

BY MR. WALZ:

Q. Have you ever prepared a trademark application?

A. No.

Q. Have you ever assisted in the preparation of a trademark application?

A. No.

Q. Under the Goods and Services heading, it reads "Medical Device; Namely, a Nebulizer"?

A. Mm-hmm. Yes.

Q. Does a nebulizer compete with the Alair System?

A. No.
Q. Would a nebulizer be marketed in the same channels as the Alair System?
A. No.
MR. HANSEN: Object to foundation.
BY MR. WALZ:
Q. Can you look next at BSC-182? I'm sorry, let's look at BSC-00187.
A. Okay.
Q. That's for the mark Ventilair?
A. Yes.
Q. Are you familiar with Hamilton Medical, Inc.?
A. No.
Q. Under the Goods and Services description or heading, it says "Medical Air Compressor for Respiratory Therapy"?
A. Yes.
Q. Would a medical air compressor compete with the Alair System?
A. No.
Q. Would a medical air compressor be marketed in the same channels as the Alair System?
MR. HANSEN: Object to foundation.

A. No.
BY MR. WALZ:
Q. Turn to BSC000189. It's for the mark Circulaire?
A. Yes.
Q. Are you familiar with the Registrant, Westmed, Inc.?
A. No.
Q. Under the heading Goods and Services, it reads "Medical Apparatus, Namely, Aerosol products comprising" -- typo, of "delivery tubes, nebulizers and reservoir bags for use in delivering pharmaceutical preparations in the form of inhalants."
Would that medical apparatus as described on Page 189 compete with the Alair System?
A. No.
Q. Would that apparatus be marketed in the same channels as the Alair System?
A. No.
MR. HANSEN: Object to foundation.
BY MR. WALZ:
Q. Can you turn to BSC-192? Are you familiar with the applicant, Novartis AG?

A. Yes.
Q. How are you familiar with them?
A. They are a pharmaceutical company that sell a variety of medications.
Q. And under the "Additional Info" it reads "Filed as intent to use."
Do you know if the Halayr mark was used in commerce?
A. I've not seen it, no.
Q. Under Goods and Services, there are two descriptions, the first one is "Pharmaceutical preparations for the treatment of disorders of the respiratory system"?
A. Yes.
Q. Does a pharmaceutical preparation for the treatment of disorders of the respiratory system compete with the Alair System?
A. No.
Q. Does the pharmaceutical preparation for the treatment of disorders of the respiratory system marketed in the same channels as the Alair system?
A. No.
MR. HANSEN: Object to foundation.
BY MR. WALZ:

Q. The second description reads "Medical apparatus, namely, inhalers for therapeutic use sold empty."

Does a medical apparatus, namely inhalers for therapeutic use sold empty, compete with the Alair System?

A. No.

MR. HANSEN: Object to foundation.

BY MR. WALZ:

Q. Does a medical apparatus, namely inhalers for therapeutic use sold empty, is that apparatus marketed in the same channels as the Alair System?

MR. HANSEN: Object to foundation.

A. No.

BY MR. WALZ:

Q. Can you turn to 195. This is, for the record, for the mark Cyclair. Are you familiar with the applicant, Novartis AG?

A. Yes.

Q. How are you familiar with them?

A. A company in the pharmaceutical space.

Q. Do you know if the mark Cyclair was ever used in commerce?

A. I've not seen it, no.

Q. And under the Goods and Services heading, the description reads "Inhalers for administering medications for use as an immunosuppressant, sold together as a unit with the medications."

Does that inhaler as described compete with the Alair System?

A. No.

Q. Does that inhaler -- is that inhaler marketed in the same channels as the Alair System?

A. No.

MR. HANSEN: Foundation.

BY MR. WALZ:

Q. Turn to Page 196. It's the mark for the mark Zolair, the applicant is identified as Novartis AG.

Do you know if the Zolair mark was ever used in commerce?

A. As written here, no.

Q. Is there another form in which the mark would have been used?

A. There is a mark pronounced Xolair spelled X-O-L-A-I-R.

Q. Okay. So --

A. This mark, no, it's not used.
Q. With that spelling it's not used?
A. Yes.
Q. Under the Goods and Services heading, the description reads "Pharmaceutical preparations for use in the treatment of" --
A. Rhinitis.
Q. -- rhinitis." Thank you.
Does that pharmaceutical preparation compete with the Alair System?
A. No.
Q. Is that pharmaceutical preparation marketed in the same channels as the Alair System?
A. No.
Q. Turn to 197. This is for the mark Eulair. The applicant is identified as BYK Gulden Lomberg, it's a German company. Are you familiar with that applicant?
A. No.
Q. The Goods and Services heading, the description reads "Pharmaceutical preparations for the treatment of respiratory diseases."
Does a pharmaceutical preparation for the treatment of respiratory diseases compete

with the Alair System?

A. No.

Q. Would a pharmaceutical preparation for the treatment of respiratory diseases be marketed in the same channels as --

MR. HANSEN: Object to foundation.

A. No.

BY MR. WALZ:

Q. -- the Alair System?

A. No.

Q. Turn to 198. The mark indicated here is Vitalaire?

A. What page?

Q. I'm sorry, I have the wrong one.

A. Page 200?

Q. 200. Sorry. Are you there?

A. Yes.

Q. Okay. So the applicant is indicated -- is identified as Liquid Air Corporation. Are you familiar with Liquid Air Corporation?

A. No.

Q. Under the Good and Services heading, the description reads "Liquid and high pressure oxygen gas provided in cylinders for hospital, clinic, and home environment use."

Do liquid and high pressure oxygen gas -- or does that product compete with the Alair System?

A. No.

Q. Would that product be marketed in the same channels as the Alair System?

A. No.

MR. HANSEN: Object to foundation.

BY MR. WALZ:

Q. If you look at Page 201, this is for the mark Xolayr. The applicant is Novartis AG. Under the Goods and Services heading, description reads "Pharmaceutical preparation for the treatment of allergic rhinitis" --

A. Rhinitis.

Q. Sorry. Thank you.

-- "and asthma."

Would a pharmaceutical preparation for the treatment of rhinitis and asthma compete with the Alair System?

A. No.

Q. Would a pharmaceutical preparation for the treatment of rhinitis and asthma be marketed in the same channel?

A. No.

Q. Look at Page 202. So this is for the mark Singulair. The applicant is identified as --

A. Merck.

Q. -- Merck & Co., correct?

Are you familiar with Merck & Co.?

A. Yes.

Q. So under the Goods and Services heading, it reads "Pharmaceutical preparations for the treatment of respiratory disorders."

Would a pharmaceutical preparation for the treatment of respiratory disorders compete with the Alair System?

A. No.

Q. Would a pharmaceutical preparation for the treatment of respiratory disorders be marketed in the same channels as the Alair System?

A. No.

MR. HANSEN: Object to foundation.

BY MR. WALZ:

Q. Can you turn to Page 236? This is for the mark Optimair.

Do you see that?

A. Yes.

Q. And the registrant is Mine Safety Appliances Company. Are you familiar with that company?

A. No.

Q. Under the Goods and Services heading it reads "Respirators other than for artificial respiration."

Would a respirator other than for artificial respiration compete with the Alair System?

A. No.

Q. Would a respirator other than for artificial respiration be marketed in the same channels as the Alair System?

A. No.

Q. And then if you can look at 248. This is for the mark Vitalaire, and the applicant is Liquid Air Corporation. You testified you're not familiar with that company?

A. Correct.

Q. Under the Goods and Services heading, the description reads "Medical equipment rental services, namely respirators, oxygen suppliers, ventilators, nebulizers and related breathing apparatus, therapy services, and retail

respirators, oxygen suppliers, ventilators, nebulizers and related breathing apparatus store services."

Do those services compete with the Alair System?

A. No.

Q. Would those services be marketed in the same channels as the Alair System?

A. No.

Q. So we spent a fair amount of time going through several pages of the Boston Scientific website --

A. Btforasthma.

Q. -- btforasthma.

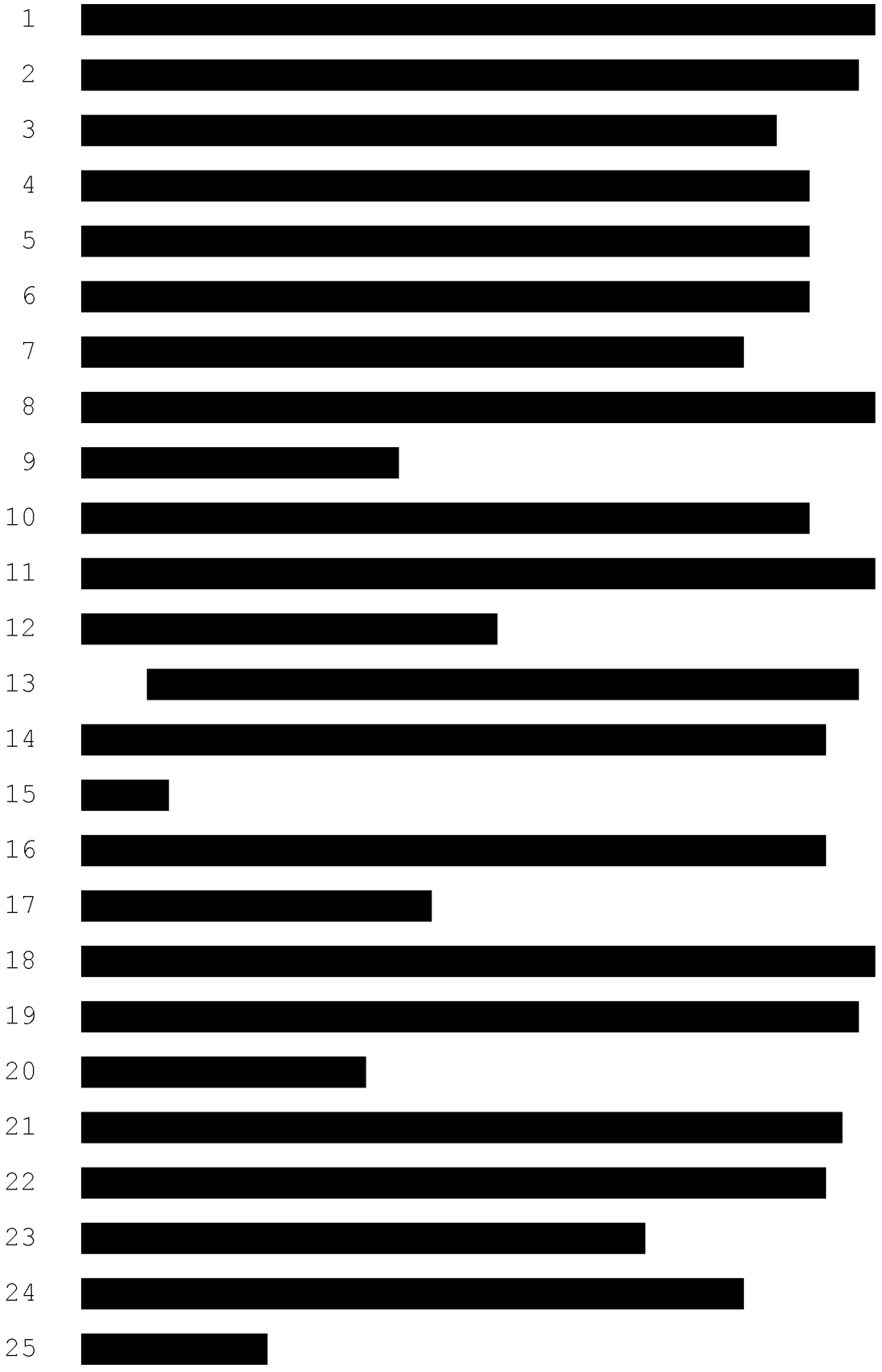
A. Right.

Q. Why was there such an emphasis placed on Bronchial Thermoplasty?

A. At the time of the market introduction, we were creating a whole new category to treat severe asthma, the first device-based therapy, and so the procedure was coined Bronchial Thermoplasty, that was what it was called in our clinical trials, and it was delivered by the Alair System, which was the product name that was used in all the clinical

trials. And so as we introduced the product to the market, we needed to create awareness for an entire new category of a way to treat asthma, which was a treatment, a mechanical-based treatment performed with the Alair System. So that the two, Bronchial Thermoplasty and the Alair System, are forever linked. The procedure is performed with the Alair System.

[redacted]



[redacted]

BY MR. WALZ:

Q. Is the mark Bronchial Thermoplasty ever used separate and apart from Alair?

A. It can be, because it describes a procedure. If we described the results of that procedure, it will -- it has to be linked with the Alair System. FDA does not approve procedures, they approve devices, and so we will never say that Bronchial Thermoplasty is approved by the FDA. Bronchial Thermoplasty delivered by the Alair System was approved by the FDA.

Q. So just so we're clear, the Bronchial Thermoplasty, when did that procedure come into existence?

A. That was prior to my arriving at Asthmatx, and I believe it was around 1999.

Q. And prior to 1999, Bronchial

Thermoplasty didn't exist?

A. Bronchial Thermoplasty did not exist until the Alair System was developed. The two are interlinked.

Q. If you look at Exhibit 18, and Page 635.

A. Yes.

Q. Are you familiar with the brands that appear on this page, Xolair, Maxair, Advair, Singulair --

A. Yes.

Q. -- and Aerobid?

A. Yes.

Q. Does the Alair System compete with any of these brands?

A. No.

Q. And is the Xolair brand a pharmaceutical therapy?

A. Yes.

Q. Same for Maxair, Advair, Aerobid, and Singulair?

A. Yes, all pharmaceutical.

Q. So you also talked about Bronchus --

A. Yes.

Q. -- and how Bronchus was split in

two --

A. Correct.

Q. -- where the asthma business went and ultimately became Asthmatx?

A. Yes.

Q. And the emphysema business went and spun off into a different company?

A. It stayed Bronchus.

Q. It stayed Bronchus?

A. Correct.

Q. Okay. Can you explain the difference between emphysema and asthma as indications?

A. So emphysema is a disease that's in a spectrum called COPD, which is a large spectrum of pulmonary disease. At one end you have chronic bronchitis, or persistent cough, that could be called COPD.

At the other end of the spectrum is emphysema, and those are patients that -- typically it's caused by smoking, and they have a deterioration of their lungs, and they get gas trapping, and they're not able to exhale properly. And so without being able to exhale, they can't take in a lot of air, so they have lower lung function. Again, it's typically

caused by smoking. It's much more prevalent in older population. And that's one disease state. And Bronchus was focused on that.

Asthma is still within the respiratory disease area, but more focused on the airways and how the airways constrict and don't let you get air in your airways. Asthma is not caused by smoking.

Q. Okay. So would an asthma patient also potentially be a COPD patient?

A. Yes. So an asthma patient who has a clear diagnosis of asthma could also have components of COPD. Again, a chronic obstructive pulmonary disease is that large catchall, if you will. So an asthma patient could develop COPD, or a constant constriction of their airway, because of having asthma for so many years. So that's an asthma patient with a COPD crossover. They're still considered asthma patients with reduced lung function.

However, if the patient has asthma but then develops emphysema, that's a different type of patient. And the Alair System will work with patients with asthma, and even a slight COPD component like the chronic cough. But if the

patient has emphysema, that is a different indication, and the Alair System would not work with a patient with emphysema.

Q. Can you look at Opposer's Exhibit Number 4? Or Applicant's. Sorry.

A. Is that yours?

Q. No.

A. Operator's Manual and Instructions for Use?

Q. Right.

A. Okay.

Q. So you testified that, as you walked through this document with Dennis, that there's training that's required of the physician?

A. Yes.

Q. And we also talked about the indications that the Alair System -- how those indications are identified in the operations manual.

A. Yes.

Q. When the training is being conducted, is it limited to asthma, or is it a little broader than just focusing on asthma in terms of --

MR. HANSEN: Sorry, go ahead. Object

to form.

A. Rephrase your question, please.

BY MR. WALZ:

Q. So on Page 664, the heading "Indications for Use," there's a specific reference to severe persistent asthma. And again, asthma is not -- and asthma that's not well controlled with inhaled --

A. Medications.

Q. -- medications. There you go.

When the training is being conducted for these -- for the physicians, they're being trained on the Alair System, is the focus of the training only specifically for asthma? Is that the only subject of the training?

MR. HANSEN: Object to form.

A. Yes. We are training the physician to use a device to treat a patient with severe asthma. That's the indication. As we go through the training, we talk about other comorbidities that the patient may have. And so part of the training includes what not to treat, or what to rule out, and teaches them about how to diagnose asthma. So we're focused on asthma, but we need to explain to them what might look

like asthma but isn't really asthma.

For example, vocal cord dysfunction. A patient wheezes when they have vocal cord dysfunction, but it's not really a problem with their lungs and their airway. So we talk about ruling out things that might look like asthma. Vocal cord dysfunction is one.

You know, other -- we talk about other comorbidities. Sleep apnea, uncontrolled sleep apnea can also cause wheezing and shortness of breath. So we kind of go through a list of what they should do to clearly identify that this patient does have asthma, and they've ruled out other problems.

BY MR. WALZ:

Q. Would any broader topics be discussed during the training?

A. Typically there's questions about COPD and emphysema, and at that point we clearly state that this is not a device intended for emphysema, but that COPD and asthma cross over, and if the patient has a component of COPD but is clearly an asthma patient, they are an appropriate candidate.

MR. HANSEN: I'll just object to the

answer as containing hearsay.

BY MR. WALZ:

Q. So you also testified that the doctors will reach out to the sales representatives to get additional information, or if they have an issue with the product they'll call the sales associate to report that to them?

A. Yes.

Q. What types of issues have been reported to the sales associates?

A. There's two types of calls that we would get from a physician that would constitute a complaint. One would be a product-related complaint; the foot pedal switch came apart, the catheter was kinked, or kinked during use, or was kinked when they took it out of the package. So a product-related complaint we would -- they would call the rep, and the rep would call it into our complaints group.

There also is an adverse event type of complaint, that if a patient was -- had a severe asthma attack after the procedure that required them to be hospitalized, the physician may call and report that there was an adverse event, the patient was hospitalized. And we -- that is a

precaution that is a known result of the procedure, and we train to that, that a patient could have an adverse event and it could cause a hospitalization. That is a big part of our training. So we encourage physicians that if that should happen, they should let us know, and then we report it. And that's part of the FDA reporting structure. So product issues, or product function complaints, as well as adverse events are both reported by physicians.

Q. Would a physician provide you with any comments other than product-related?

A. Physicians often ask about certain patients, and would they be appropriate for this procedure. Many of our -- many types of patients that we don't have data, that we did not treat in our clinical trial, physicians may ask would this be patient be appropriate, and at that point we often refer them to a third party physician experienced in the procedure to give medical advice.

Q. What type of comments from physicians have you received on the market in terms of what treatments are available and what products are available in the market?

A. So we get comments from physicians usually asking about who is the appropriate patient for this procedure, how does -- you know, what is the success rate, or what are the known benefits of this versus, you know, other possible medications that might treat asthma.

When there's a new publication about Bronchial Thermoplasty, we will get questions from physicians. There are publications both pro and con about Bronchial Thermoplasty, and there have been, you know, physicians that have taken a negative position on their belief of the benefit of BT, and we get questions about those publications.

There was a recent publication about the Holaira device, and we got questions from physicians in China and in Europe asking what is this device, and when they read the description asking what is this and, you know, how does this differ from Bronchial Thermoplasty. So people were asking about, you know, that device, we did get questions recently.

Q. So were the questions directed at -- I guess what was the -- were the questions directed at an association with Boston

Scientific?

MR. HANSEN: Object to the request for hearsay.

A. The questions came from customers, physicians that use our product today, and they questioned their local representative and asked -- and brought up this article, and talked about targeted long denervation for the treatment of emphysema, and said, you know, how is this different than what we're doing with the Alair System for asthma.

BY MR. WALZ:

Q. Just going back to the website, the btforasthma website, you had indicated there are a number of links that are also on that website.

A. Yes.

Q. And clicking on some of those links -- well, let's look at a specific one. If you can look at Applicant's Exhibit 15.

A. Yes.

Q. So in the left drop-down categories, there's a specific reference to the Alair System.

A. Yes.

Q. So that's an example of a link you

could click on that would take you to another page?

A. Yes, description of the Alair System, more detailed of what the system components are.

Q. So what's the purpose of the btforasthma website?

A. The website was primarily designed for patient and physician awareness of a new treatment for asthma, so Bronchial Thermoplasty being the broad category of an innovative new procedure, first non-medication procedure for asthma, and it's performed with the Alair System, so the two are linked. And Bronchial Thermoplasty, being the procedure, was the easier way to kind of orient the different categories. And within each category, we get into more detail about how the procedure is performed, what the device is like, what the trials were, how were the trials performed, how was the device used in the trials. And so Alair is woven throughout the entire website.

MR. WALZ: I have no further questions.

MR. HANSEN: I have no further questions.

(Whereupon, the deposition was concluded at 1:48 p.m.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 9th day of April, 2015, at 8:50 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 20th day of April, 2015.

Maureen O Pollard

MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

- - - - - - -

PAGE	LINE	CHANGE
47	13	expense changed to experience
REASON:		used wrong word
102	13	Alair changed to Holaira
REASON:		used wrong word
REASON:		
REASON:		
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ACKNOWLEDGMENT OF DEPONENT

I, Karen M. Passafaro, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

/Karen M Passafaro/ 5/19/15

KAREN M. PASSAFARO DATE

Subscribed and sworn
To before me this
19TH day of MAY, 2015.
My commission expires: MARCH 20, 2019

Allen D. Coffin

Notary Public

ALLEN D. COFFIN
COMM. #2103980
NOTARY PUBLIC - CALIFORNIA
SONOMA COUNTY
My Comm. Expires March 20, 2019

JER-1 JER-1

LAWYER'S NOTES

PAGE	LINE	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Alere Medical Incorporated, Petitioner, v. Asthmatx, Inc., Respondent.	Cancellation No. Registration Nos. 2856168 3380080

PETITION FOR CANCELLATION

Alere Medical Incorporated, a California corporation having a place of business at 595 Double Eagle Court, Suite 1000, Reno, Nevada 89521 (hereinafter "Petitioner"), believes that it will be damaged by Registration Nos. 2856168 and 3380080 for the mark ALAIR, and hereby petitions to cancel same.

The grounds for this petition are as follows:

1. Respondent is the owner of Registration No. 2856168 of the mark ALAIR for "medical therapeutic devices for use in the treatment of pulmonary diseases, namely, catheters, probes, generators, bronchoscopes, and electrodes" in International Class 10, which issued on June 22, 2004.

2. Respondent is the owner of Registration No. 3380080 of the mark ALAIR for "Training and teaching in the field of surgery and treatment of pulmonary diseases, namely training and teaching in the use and operation of medical devices for bronchial surgery or

treatment, and distribution of course materials, namely printed materials and electronic media, in connection therewith" in International Class 41, which issued on February 12, 2008.

3. Petitioner is the owner of Registration No. 2659940 of the mark ALERE for "medical monitoring apparatus used to monitor and communicate data such as weight, blood pressure, blood glucose levels, other blood chemistry data, heart rate, EKG, coagulation time, peak flow, or other measurements of respiratory function in patients with chronic diseases such as asthma, diabetes, obesity, chronic hypertension, chronic renal disease and chronic obstructive pulmonary disease" in International Class 10, which issued on December 10, 2002.

4. Petitioner is the owner of Registration No. 3530814 of the mark ALERE for "health care services" in International Class 44, which issued on November 11, 2008.

5. Pursuant to Trademark Rule 2.122(d), print-outs from the USPTO TARR, TESS, and Assignment databases for Petitioner's Registrations Nos. 2659940 and 3530814 are attached to this Petition for Cancellation.

6. Petitioner has widely used, promoted and advertised its mark ALERE in connection with the goods and services specified in Paragraphs 3 and 4, *supra*.

7. Petitioner has continuously used its ALERE mark in commerce since prior to the original filing dates of Registrations Nos. 2856168 and 3380080, and since prior to the dates of first use in commerce claimed in connection with Registrations Nos. 2856168 and 3380080.

8. Petitioner has invested significant time, money, and effort in the promotion and use of its mark ALERE. As a result, Petitioner has built up an extensive reputation and goodwill in the ALERE mark in relation to Petitioner's goods and services.

9. The ALAIR mark that is the subject of Registrations Nos. 2856168 and 3380080 is confusingly similar to Petitioner's mark ALAIR.

10. The goods and services set forth in Registrations Nos. 2856168 and 3380080 are similar and/or related to the goods and services with which Petitioner has used and is using its ALERE mark.

11. Respondent's use of the mark ALAIR for the goods and services identified in Registrations Nos. 2856168 and 3380080 is likely to cause confusion, mistake or deception as to the source of Respondent's goods and services, all to Petitioner's damage. Furthermore, customers or potential customers are likely to believe that Respondent's goods and services are sponsored or approved by or affiliated with Petitioner when that is not the case. Any dissatisfaction with Respondent's goods or services will reflect upon and damage the goodwill and reputation embodied in Petitioner's ALERE mark.

WHEREFORE, Petitioner prays that Registrations Nos. 2856168 and 3380080 be canceled and that this Petition for Cancellation be sustained. The filing fee for this Petition for Cancellation in the amount of $600.00 ($300.00 per class) is enclosed.

Respectfully submitted,

Alere Medical Incorporated

Joshua S. Jarvis
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000

Dated: June 18, 2009

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the Petition for Cancellation and corresponding USPTO TARR, TESS, and Assignment database printouts were served upon Respondent:

Asthmatx Inc.
1340 Space Park Way
Mountain View, CA 94043

and the correspondent of record associated with Registration Nos. 2856168 and 3380080:

E. Lynn Perry
Perry IP Group A Law Corporation
4 Embarcadero Center, 39th Floor
San Francisco, CA 94111

by FedEx this date of June 18, 2009.

Joshua S. Jarvis

B3639096.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ALERE MEDICAL CORPORATION, Petitioner, v. ASTHMATX, INC., Respondent.	)	Cancellation No. 92051129 Mark: ALAIR Reg. Nos. 2856168 and 3380080

ANSWER

ASTHMATX, INC., Respondent, hereby answers the Petition to Cancel filed by ALERE MEDICAL CORPORATION, Petitioner, as follows. Respondent is without sufficient knowledge or information concerning the corporate status and place of business of Petitioner, and on that basis denies the same, and denies that Petitioner is or would be damaged by registration of ALAIR Reg. Nos. 2856168 and 3380080 (the "Registrations"). Further answering, Respondent alleges:

1. Respondent admits the allegations in paragraph 1 of the Petition.

2. Respondent admits the allegations in paragraph 2 of the Petition.

3. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Petition, and on that basis denies the same.

4. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 4 of the Petition, and on that basis denies the same.

5. Respondent admits that copies of print-outs from the USPTO TARR, TESS, and Assignment databases for Reg. Nos. 2659940 and 3530814 are attached to the Petition. Respondent is without knowledge or information sufficient to form a belief as to the truth or

falsity of the remaining allegations contained in paragraph 5 of the Petition, and on that basis denies the same.

6. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 6 of the Petition, and on that basis denies the same.

7. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 8 of the Petition, and on that basis denies the same.

8. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 8 of the Petition, and on that basis denies the same.

9. Respondent denies the allegations contained in paragraph 9 of the Petition.

10. Respondent denies the allegations contained in paragraph 10 of the Petition.

11. Respondent denies the allegations contained in paragraph 11 of the Petition.

AFFIRMATIVE DEFENSES

1. The Petition fails to state a claim upon which relief can be granted.

2. The marks themselves and the goods and services to which they are applied are sufficiently different that there is no likelihood of confusion.

3. There is no likelihood of confusion because the parties' marks have co-existed for several years with no actual confusion.

4. On information and belief, Respondent used its mark ALAIR in connection with medical devices and related services in relation to pulmonary diseases prior to any such use by Petitioner, so Respondent has priority over Petitioner. Therefore, the Petition fails due to lack of superior rights.

5. Petitioner lacks standing because there is no basis for Petitioner's belief that it is damaged by Respondent's registrations.

6. Petitioner is estopped from prevailing in this action by the equitable defense of laches.

7. Petitioner is estopped from prevailing in this action by the equitable defense of acquiescence.

8. Petitioner is estopped from prevailing in this action by the equitable defense of unclean hands in that Petitioner's sole purpose in filing the Petition is to stop Respondent's Reg. No. 2856168 from becoming incontestable and to use the Petition as leverage concerning non-U.S. matters.

WHEREFORE, Respondent prays that the Cancellation be dismissed with prejudice.

Respectfully submitted,

E. Lynn Perry
Attorneys for Respondent
ASTHMATX, INC.

Perry IP Group ALC
4 Embarcadero Center
39th Floor
San Francisco, CA 94111
415-398-6300 (tel.)
415-398-6306 (fax)

CERTIFICATE OF SERVICE BY MAIL

I am over the age of 18 and not a party to the within action. I am employed in the County of San Francisco, State of California by Perry IP Group ALC. My business address is 4 Embarcadero Center, 39th Floor, San Francisco, California 94111.

On the date indicated below, I served the following entitled document:

ANSWER

by placing a true and correct copy thereof in a sealed envelope addressed as follows:

Charles E. Weinstein, Esq.
Foley Hoag LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210-2600

I am readily familiar with the firm's business practice for collection and processing of correspondence for mailing with the United States Postal Service. On this day, I placed for collection and processing the above document to be deposited with the United States Postal Service in the ordinary course of business. And in the ordinary course of the firm's business, such correspondence is deposited with the United States Postal Service the same day that it is collected.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on September 1, 2009 at San Francisco, California.

E. Lynn Perry

Boston Scientific

ALAIR™

Bronchial Thermoplasty Catheter

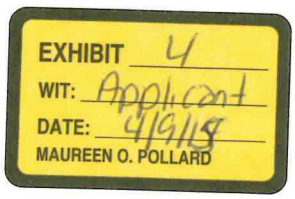


TABLE OF CONTENTS

ALAIR™

Bronchial Thermoplasty Catheter

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

FOR PROFESSIONAL USE ONLY

The Alair Catheter must be used by a physician who has training and experience in performing bronchoscopic procedures.

WARNING

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific Corporation (BSC) representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

ALAIR BRONCHIAL THERMOPLASTY SYSTEM DESCRIPTION

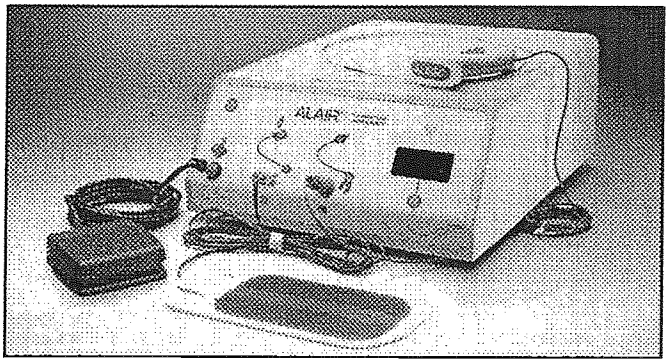


Figure 1. The Alair Bronchial Thermoplasty System

The Alair Bronchial Thermoplasty System ("Alair System"), manufactured by Boston Scientific Corporation, consists of the Alair Catheter and the Alair Controller System, as described below:

Alair Catheter: The Alair Catheter Model ATS 2-5 ("Catheter") is provided sterile and is a SINGLE-USE ONLY, disposable device. The Catheter delivers energy from the Controller to the desired site in the airway and relays temperature feedback to the Controller. The Alair Catheter Model ATS 2-5 is designed to be used with the Alair RF Controller Model ATS 200.

Alair Controller System

Alair Radiofrequency (RF) Controller: The Alair RF Controller Model ATS 200 ("Controller") is designed to provide controlled delivery of RF energy to the Alair Catheter. Energy from the Controller is delivered to the Catheter through the electrical cable attached to the proximal end of the Catheter handle. Actual power delivered is automatically modulated by the Controller based on temperature control algorithms. The Controller delivers low-power, temperature controlled RF energy to the airway at a predetermined temperature setting for a predetermined time period. The Controller incorporates hardware and software features that limit current, voltage, power, energy, time and temperature during each application of RF energy. The Controller is not intended to come in contact with the patient and therefore is not provided as a sterile device. For information on the installation, use, and other technical specifications, please read the Alair Radiofrequency Controller Operator's Manual for Model ATS 200.

Footswitch: The Controller is used with a footswitch that allows the operator to start and stop the delivery of RF energy. The Controller is designed to be used with the compatible footswitch provided by BSC. The footswitch is not intended to come into contact with the patient and therefore is not provided as a sterile device.

Patient Return Electrode: The Controller is designed to be used with a gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. The patient return electrode is used to complete the return path for the electrical current. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs). Examples of acceptable patient return electrodes include Valleylab™ E7506 and ConMed™ 51-7310. Follow the directions for use (DFU) packaged with the patient return electrode

Contents

One (1) ALAIR Catheter Model ATS 2-5

INDICATION FOR USE

The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists.

BRONCHOSCOPE REQUIREMENTS

The Catheter is designed to be used with high-frequency compatible flexible bronchoscopes that have a minimum 2.0 mm working channel, and recommended 5.3 mm or less outer diameter.

MECHANISM OF ACTION

Airway smooth muscle (ASM) consists of muscle tissue within the airway walls in the lung. Contraction of the ASM is a main cause of airway constriction that leads to difficulty in breathing during asthma attacks. Severe asthma patients also experience an increase in ASM mass. This increase, together with inflammation of the airways, combines to thicken airway walls, which decreases the inside diameter of the airways when the ASM contracts. The resulting decrease in airway diameter causes increased resistance to airflow and further contributes to difficulty in breathing during asthma attacks.

The Alair™ System is used to deliver thermal energy to the airway wall, to heat the tissue in a controlled manner in order to reduce ASM mass. Bronchial thermoplasty is intended to reduce, debulk, or partially eliminate smooth muscle tissue. In preclinical studies (Danek et al. 2004[1], Brown et al. 2005[2]), the reduction of ASM has been shown to decrease the ability of the airways to constrict/contract, reduce resistance to airflow and responsiveness of the airway, and increase the resting diameter of the airway.

CONTRAINDICATIONS ⚠

Patients with the following conditions should not be treated:

- Presence of a pacemaker, internal defibrillator, or other implantable electronic devices,
- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines,
- Patients previously treated with the Alair System should not be retreated in the same area(s). No clinical data are available studying the safety and/or effectiveness of repeat treatments.

Patients should not be treated while the following conditions are present:

- Active respiratory infection,
- Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days,
- Known coagulopathy,
- As with other bronchoscopic procedures, patients should stop taking anticoagulants, antiplatelet agents, aspirin and NSAIDS before the procedure with physician guidance.

WARNINGS ⚠

Read these directions for use in conjunction with the Alair RF Controller Model ATS 200 Operator's Manual before using the Alair Bronchial Thermoplasty System. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient.

1 Prior to performing the procedure, ensure appropriate training, equipment, medications and staff are in place to handle any potential bronchoscopic, respiratory or anesthesia related emergencies. The Alair System should only be used in a fully equipped bronchoscopy suite with access to full resuscitation equipment to handle hemoptysis, pneumothorax, and other respiratory complications including acute exacerbation of asthma and respiratory failure requiring intubation.

2 Do not deliver energy if the Catheter's electrode array is in contact with a metal object. This may result in harm or injury to the patient and/or operator.

3 Do not advance the Catheter within the bronchoscope if significant resistance is felt, as this may result in harm or injury to the patient and/or cause damage to the Catheter and/or bronchoscope.

4 Do not advance the Catheter into bronchi in which the Catheter cannot be seen under bronchoscopic vision. Advancing the Catheter beyond this region may cause patient harm or injury such as pneumothorax or pneumomediastinum.

5 Do not reposition the bronchoscope with the Catheter advanced beyond the distal end of the bronchoscope as this may result in patient harm or injury.

6 Use of the Alair Catheter with a non-Alair Controller may result in harm or injury to the patient and/or operator, or may result in product malfunction.

7 Do not treat the right middle lobe because of the potential susceptibility of the right middle lobe to transient obstruction as a result of inflammation or edema due to certain anatomical characteristics. The narrow diameter of the lobar bronchus and acute take-off angle may create poor conditions of drainage that may cause patient harm or injury such as atelectasis or difficulty in re-inflation (Right Middle Lobe Syndrome).

8 No modification of this equipment is allowed.

PRECAUTIONS ⚠

1 The Alair Catheter is provided sterile and is SINGLE USE ONLY. Do not use the Catheter if the package is opened, torn, or damaged. Use of a Catheter from damaged packaging may result in patient harm or injury. **Do not re-sterilize, reprocess or reuse** the Catheter, as this may result in patient harm or injury, transmittal of infectious disease or product malfunction.

2 Do not use the Catheter if it comes in contact with a surface that is not aseptic (e.g. floor). This may result in patient infection.

3 Do not use the Catheter if it is damaged or irregular. Use of a damaged or irregular Catheter may result in patient harm or injury.

4 Do not use the Catheter if the marker bands are not visible (See Operational Instructions, Figure 5).

5 Use care when handling the Catheter to avoid kinking the Catheter shaft.

6 Avoid deflecting the bronchoscope while the electrode array is within the bend of the bronchoscope's working channel as this may result in damage to the Catheter and failure of the Catheter to operate properly.

7 Before inserting or removing the Catheter from the bronchoscope, ensure the electrode array is relaxed. Do not use the Catheter if the electrode array does not expand or relax properly (See Operational Instructions, Figures 6 and 7).

8 Before delivering energy, make certain that all electrodes are in contact with the airway wall.

9 Caution should be taken in patients with the following conditions due to a potential increased risk of adverse events that may be associated with the procedure. Patients with these conditions were not studied in the pivotal trial and the safety of Alair treatment for such patients has not been determined:

- Post-bronchodilator $FEV_1 < 65\%$ predicted.
- Other respiratory diseases including emphysema, vocal cord dysfunction, mechanical upper airway obstruction, cystic fibrosis or uncontrolled obstructive sleep apnea.
- Use of short-acting bronchodilator in excess of 12 puffs per day within 48 hours of bronchoscopy (excluding prophylactic use for exercise).
- Use of oral corticosteroids in excess of 10 milligrams per day for asthma.
- Increased risk for adverse events associated with bronchoscopy or anesthesia, such as pregnancy, insulin dependent diabetes, epilepsy or other significant co-morbidities, such as uncontrolled coronary artery disease, acute or chronic renal failure, and uncontrolled hypertension.

- Intubation for asthma, or ICU admission for asthma within the prior 24 months.
- Any of the following within the past 12 months:
  i. 4 or more lower respiratory tract infections (LRTI)
  ii. 3 or more hospitalizations for respiratory symptoms
  iii. 4 or more OCS pulses for asthma exacerbation

10 The Alair™ System should only be used by clinicians who are experienced in bronchoscopy and have undergone adequate training with the device.

11 The Alair System should only be used in patients stable enough to undergo bronchoscopy in the judgment of their clinician.

12 Follow local governing ordinances and your institution's biohazard procedures regarding disposal of the Alair Catheter and patient return electrode.

CLINICAL STUDIES

Objectives

The pivotal study was a multi-center, randomized, double-blind, sham-controlled study to demonstrate the safety and effectiveness of the Alair System in a population of subjects with severe asthma.

Effectiveness Endpoints

The primary effectiveness endpoint was the difference between treatment (Alair) and control (Sham) groups in the change in the Asthma Quality of Life Questionnaire (AQLQ) score between baseline and the average of 6-, 9-, and 12-month follow-up visits (integrated AQLQ score). Other endpoints included: rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. In addition, several safety endpoints were considered for effectiveness; these endpoints included rates of asthma (multiple symptoms)* adverse events, Unscheduled Physician Office visits for respiratory symptoms, Emergency Room visits for respiratory symptoms, and Hospitalizations for respiratory symptoms.

* "Asthma (multiple symptoms)" is defined as occurrence or worsening of shortness of breath, wheeze, cough, productive cough, or some combination of these.

Methods

This was a multicenter, randomized (2 Alair, 1 Sham), double-blind, sham-controlled clinical trial comparing the effects of treatment with the Alair System to a Sham treatment in subjects that were optimized to conventional therapy of inhaled corticosteroids (ICS) and long-acting β_2-agonists (LABA). All subjects included in the Study were taking ICS (> 1000 µg beclomethasone or equivalent per day) and LABA (≥ 100 µg salmeterol or equivalent per day), and were still symptomatic. Subjects in the Alair and Sham groups were administered the Alair treatment and Sham bronchoscopies, respectively, by an unblinded bronchoscopy team in 3 separate bronchoscopy sessions. Each bronchoscopy session was separated by at least 3 weeks. All bronchoscopy sessions were administered under local anesthesia with sedation. Subjects had follow-up visits with blinded asthma assessment teams at 6-weeks, 12-weeks, 6-months, 9-months, and 12-months after the final bronchoscopy session. All subjects were prescribed to take 50 mg of oral prednisone or prednisolone (or equivalent) each day for 5 days covering the 3 days before the bronchoscopy session, the day of the bronchoscopy session, and the day after the bronchoscopy session (prophylactic indication).

Statistical Plan

Primary and secondary endpoints, as well as adverse events were analyzed using Bayesian statistics. The Posterior Probability of Superiority was calculated for the primary and secondary endpoints, as well as safety outcomes.

Patient Population

Enrollment was limited to patients with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA. Subjects may have been taking up to 10 milligrams of oral corticosteroids per day. Study subjects were required to meet the following patient selection criteria:

Key Entry Criteria

Inclusion

1. Adult; age 18-65 years.
2. Asthma requiring regular maintenance medication that includes inhaled corticosteroids (greater than 1000 µg beclomethasone per day or equivalent) and long-acting β_2-agonists (at least 100 µg salmeterol per day or equivalent), with or without other asthma medications. Oral corticosteroids at a dosage of up to, but not greater than 10 mg per day, or 20 mg every other day are acceptable.
3. Asthma Quality of Life Questionnaire Score during the Baseline Phase of 6.25 or less.
4. Pre-bronchodilator forced expiratory volume in one second ≥ 60% predicted (after patients stabilized on inhaled corticosteroids and long-acting β_2-agonists during the Baseline Phase).
5. Non-smoker x 1 year or greater (if former smoker, less than 10 pack years total smoking history).

Exclusion

1. Post-bronchodilator FEV_1 < 65% predicted.
2. Three or more hospitalizations for exacerbations of asthma in the previous year; OR a history of life-threatening asthma, defined by past intubations for asthma, or intensive care unit admission for asthma within the prior 24 months.
3. History of recurrent lower respiratory tract infection requiring antibiotics (more than 3 in the past 12-Months).
4. History of recurrent oral steroid use for asthma (4 or more pulses of oral steroids in the past 12-Months).

Demographics

A total of 297 subjects between the ages of 18 and 65 were enrolled and randomized (2 Alair: 1 Sham) in this study. One hundred and ninety (190) subjects received the Alair treatment and 98 subjects received the Sham control treatment (Intent-to-Treat population). The Sham procedure was identical to the Alair procedure except that no energy was delivered through the Catheter.

There were no statistical differences in demographic measures between the Alair and Sham groups. Subject demographics are described in Table 1.

	Alair (n=190)	Sham (n=98)
Age (years) (Mean ± SD)	41 ± 12	41 ± 12
Gender		
Male	81 (43%)	38 (39%)
Female	109 (57%)	60 (61%)
Race/Ethnicity		
Caucasian	151 (80%)	72 (74%)
African American / Black	19 (10%)	15 (15%)
Hispanic	6 (3%)	4 (4%)
Asian	4 (2%)	1 (1%)
Other	10 (5%)	6 (6%)
Height (cm) (Mean ± SD)	167 ± 9	167 ± 10
Weight (kg) (Mean ± SD)	82 ± 18	82 ± 20

Table 1: Subject Demographics (Intent-to-Treat Population)

Effectiveness Results

Effectiveness analyses were performed for both the Intent-to-Treat (ITT) population and Per-Protocol (PP) population. The ITT population consisted of all randomized subjects who have been administered at least one bronchoscopy. The PP population excluded all subjects in the ITT population who met any of the following criteria:

- Have taken any interfering concomitant medications.
- Have undergone other interfering treatments.
- Did not attend one of the 6-, 9-, 12-month visits, with the exception of a discontinuation from the Study due to an adverse event related to Study treatment.
- Had missed one or more bronchoscopy procedures.

Effectiveness Endpoints

Although the clinical study was powered only for the primary effectiveness endpoint (see below), several effectiveness endpoints and safety endpoints that could also be considered effectiveness endpoints demonstrated clinically meaningful differences in favor of the Alair group compared to the Sham group. The effectiveness endpoints were rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. The safety endpoints considered for effectiveness were rates of asthma, emergency room visits for respiratory symptoms, and hospitalization rates for respiratory symptoms.

Steroid Exacerbations[a] (Severe Exacerbations Requiring Systemic Corticosteroids) (ITT Population)

During the Post-Treatment Phase, the severe exacerbation rate for the Steroid Exacerbations was 0.48 exacerbations/subject/year in the Alair group and 0.70 exacerbations/subject/year in the Sham group [95% CI (Sham - Alair): -0.031, 0.520]. During the Post-Treatment Phase, the proportion of subjects experiencing Steroid Exacerbations was 26% in the Alair group and 40% in the Sham group [95% CI (Sham - Alair): 2.1%, 25.1%].

Steroid Exacerbation rates (annualized rate) and proportion of patients experiencing Severe Exacerbations for the Post-Treatment Phase are presented graphically in Figure 2.

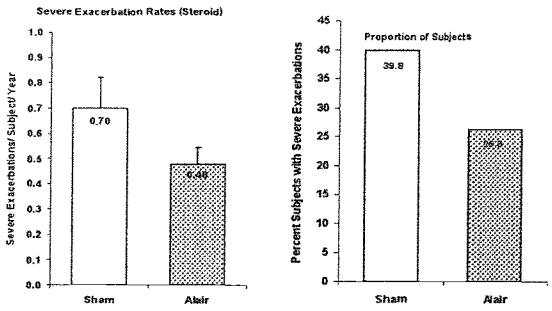


Figure 2: Severe Exacerbations during the Post-Treatment Phase

[a]**Steroid Exacerbations** = Exacerbations treated with oral or intravenous corticosteroids, OR a doubling of the baseline inhaled corticosteroid dose for at least 3 days, OR any temporary increase in the dosage of oral corticosteroids for a subject taking maintenance oral corticosteroids at Study entry.

Annualized rates of exacerbations per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit.

Days Lost from Work, School, or Other Daily Activities due to Asthma Symptoms (ITT Population)

During the Post-Treatment Phase, subjects in the Alair group lost an average of 1.3 days/year/subject from work, school, or other daily activities due to asthma symptoms, compared to the Sham group that lost 3.9 days/year/subject (annualized rates per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit) [95% CI (Sham - Alair): 0.425, 6.397].

Safety Endpoints that Demonstrated Effectiveness

Measures such as Emergency Room visits and Hospitalizations for respiratory symptoms are generally considered to be important measures of safety, especially if an intervention results in an increase in the rate of one or more of these events. However, these measures can also be considered important measures of effectiveness if an intervention results in a measurable decrease in the rate of one or more of these events. During longer-term follow-up (> 6 weeks after the last Alair™ treatment), there was a reduction in asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): -0.01, 0.001], Emergency Room visits for respiratory symptoms [95% CI (Sham - Alair): 0.11, 0.83], and Hospitalizations for respiratory symptoms (event rate per group) [95% CI (Sham - Alair): 0.025, 0.172], presented graphically in Figure 3.

There was a reduction in the proportion of subjects having asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): 4.0%, 27.3%], and in the proportion of subjects having Emergency Room visits for respiratory symptoms in the Alair group (3.7% in the Alair group compared to 15.3% in the Sham group) [95% CI (Sham - Alair): 4.6%, 19.7%].

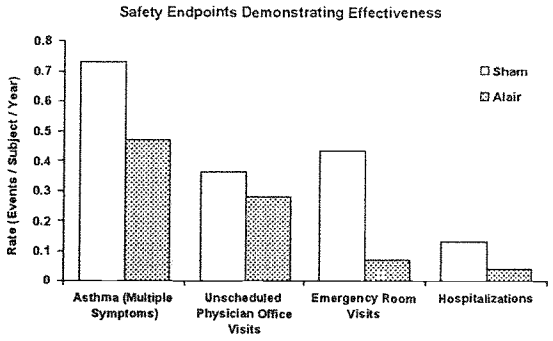


Figure 3: Safety Endpoints demonstrating Effectiveness (ITT Population)

Primary Effectiveness Endpoint – Integrated AQLQ Score

The difference between the Alair and Sham groups in the average change in AQLQ score from Baseline at the 6-, 9-, and 12-month follow-up visits was 0.210 [95% CI (Alair - Sham): -0.025, 0.445]. The pre-specified Posterior Probability of Superiority for the difference between the groups was 96.4%. For the ITT population, the difference between the groups had a Posterior Probability of Superiority of 96.0%, and for the PP population, the difference between the groups had a Posterior Probability of Superiority of 97.9%, demonstrating an improvement in the Asthma Quality of Life in the Alair group compared to Sham. The results for the change from Baseline of the Integrated AQLQ score for the Intent-to-Treat and Per Protocol populations are summarized in Table 2.

Population	Difference Between Groups in Integrated AQLQ Score (Posterior Mean, 95% CI)	Posterior Probability of Superiority (%)
ITT (Intent-to-Treat) (Alair N=190, Sham N=98)	0.210 (-0.025, 0.445)	96.0
PP (Per Protocol) (Alair N=173, Sham N=95)	0.244 (0.009, 0.478)	97.9

Table 2: Primary Effectiveness Endpoint: Integrated AQLQ Score

ADVERSE EVENTS IN PIVOTAL STUDY

Patient Population

The Alair™ System was evaluated in a randomized, double-blind, sham-controlled, multi-center clinical study – the Asthma Intervention Research 2 (AIR2) Trial. A total of 297 subjects with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA were randomized – 196 subjects in the Alair group and 101 subjects in the Sham group. (See the Clinical Data section for key entry criteria.) The Sham procedure was identical to the Alair procedure except that no energy was delivered to the Catheter in the sham procedure.

Safety analyses were performed for the Intent-to-Treat (ITT) population (288 subjects) that consisted of all randomized subjects who have been administered at least one bronchoscopy.

Observed Adverse Events

The safety of the Alair System was assessed by comparing adverse event profiles of the Alair and Sham group subjects. Adverse event profiles are compared for the Treatment Phase (day of first bronchoscopy procedure to 6 weeks after the last bronchoscopy procedure) and Post-Treatment Phase (6 weeks after the last bronchoscopy to the 12 month follow-up visit).

Adverse events (whether considered procedure-related or not procedure related by the investigator) occurring with ≥ 3% incidence in the Alair group are presented for 288 patients in Table 3.

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Average duration of period (days)	84		322	
Ear, Nose, and Throat				
Upper respiratory tract infection	20	11	30	26
Nasopharyngitis	5	7	11	5
Throat irritation	5	12	1	3
Viral upper respiratory tract infection	4	2	6	7
Sinusitis	3	5	6	7
Acute Sinusitis	3	2	4	8
Pharyngolaryngeal pain	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
Lower Respiratory				
Asthma (Multiple Symptoms)	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Dyspnea	11	6	2	1
Chest discomfort	9	10	2	1
Lower respiratory tract infection	8	2	3	6
Productive cough	7	9	3	4
Atelectasis	5	0	0	0
Bronchitis	4	2	7	5
Hemoptysis	3	0	0	0
Neurology				
Headaches	14	9	5	3
Anxiety	4	0	1	2
Gastrointestinal				
Dyspepsia	4	2	2	4
Nausea	3	4	1	1

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Non-site specific				
Influenza	4	2	4	12
Pyrexia (fever)	4	2	0	1
Other				
Back pain	5	6	3	5
Hypertension	3	2	3	3
Urinary tract infection	1	1	3	1

Table 3: Adverse Events with ≥ 3% Incidence (% of subjects) in the Alair Group

* Treatment phase represents adverse events reported between the first bronchoscopy and 6-weeks post last bronchoscopy.

** Post-Treatment phase represents adverse events reported between 6-weeks post last bronchoscopy and the 12 month visit.

Respiratory adverse events occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair group included abnormal breath sounds, acute bronchitis, bronchial obstruction, bronchospasm, discolored sputum (blood-tinged sputum), epistaxis, hypoxia, increased upper airway secretion, nasal congestion, operative hemorrhage, pneumonia, pulmonary congestion, rhinorrhea, viral lower respiratory tract infection, and viral pharyngitis.

Non-respiratory adverse events occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair group included abdominal pain, acne, allergic dermatitis, arthralgia, back injury, candidiasis, conjunctivitis, cystitis, depression, diarrhea, dizziness, fatigue, food poisoning, gastritis, gastroenteritis, gastroesophageal reflux disease, gastrointestinal infection, heart palpitations, herpes simplex, hiccups, hyperglycemia, hypersensitivity, hypotension, injury, insomnia, intervertebral disc protrusion, joint sprain, ligament rupture, migraine, muscle strain, musculoskeletal pain, nephrolithiasis, oral candidiasis, pain in extremity, peripheral edema, procedural pain, rash, skin laceration, tendonitis, tonsillitis, tooth abscess, tooth extraction, tooth infection, toothache, tremor, viral tonsillitis, and vomiting.

There may be other risks associated with the procedure and attendant anesthesia and medications. Please consult the manufacturers' directions for use for the equipment and medications used in association with the bronchial thermoplasty procedure for relevant indications, warnings, precautions, and adverse events.

During the Treatment Phase in the AIR2 Trial, there was a transient increase in respiratory adverse events, including asthma (multiple symptoms), upper respiratory tract infection, atelectasis, lower respiratory tract infection, wheezing, hemoptysis, and anxiety in the Alair group compared to the Sham group. There was a lower incidence of throat irritation in the Alair group compared to the Sham group. There were 7 instances of hemoptysis defined as > 5.0 mL (1.3% of bronchoscopies) of which 2 occurred on the day of the procedure, 2 occurred within 3 days, 2 occurred at 2 weeks, and one occurred on Day 31 after the procedure. The greatest amount of hemoptysis observed was a cumulative total of 150 mL that occurred over 5 days and was treated with bronchial artery embolization.

During the Treatment Phase (~12 weeks period), the rate of Unscheduled Physician Office visits (events / subject / 12 weeks) in the Alair group was 0.230 compared to 0.133 in the Sham group. The rate of Hospitalizations for respiratory symptoms (events / subject / 12 weeks) was 0.086 in the Alair group compared to 0.028 in the Sham group. The rate of Emergency Room visits for respiratory symptoms (events / subject / 12 weeks) was 0.062 in the Alair group compared to 0.075 in the Sham group.

During the Post-Treatment Phase in the AIR2 Trial, there was a lower incidence of respiratory symptoms in the Alair group compared to the Sham group, including a 36% reduction in asthma (multiple symptoms) events and proportion of subjects with asthma (multiple symptoms) events. There was also a lower incidence of influenza, and a greater incidence of nasopharyngitis, in the Alair group compared to the Sham group.

High Resolution Computed Tomography (HRCT) Results

In the 150 subjects (100 Alair group and 50 Sham group) assigned to HRCT scan examinations, at 1-year, there were no difference in signs of gas trapping or consolidation and there was no evidence of bronchiectasis. A difference was seen in bronchial wall thickening without gas trapping which occurred only in the Sham subjects (4%).

Summary of Clinical Findings

Results from the clinical study which evaluated the effectiveness and safety of the Alair™ System in subjects with severe asthma demonstrated that Alair treatment resulted in clinically significant reductions in severe exacerbations that required systemic steroids, the percent of subjects experiencing the severe exacerbations, the number of Emergency Room visits for respiratory symptoms, the percent of subjects experiencing Emergency Room visits for respiratory symptoms, Hospitalizations for respiratory symptoms, and days lost from school/work/other daily activities due to asthma symptoms. Although bronchial thermoplasty was associated with an increased rate of respiratory adverse events during the Treatment Phase (primarily related to asthma), in the Post-Treatment Phase, a smaller proportion of patients treated with bronchial thermoplasty experienced respiratory adverse events, including asthma (multiple symptoms).

HOW SUPPLIED

The Alair Bronchial Thermoplasty System Catheter Model ATS 2-5 is supplied sterile and is for SINGLE USE ONLY. Do not re-sterilize, reprocess or reuse the Catheter, as this may result in patient harm or injury, transmittal of infectious disease, or product malfunction. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Rotate inventory so that product is used prior to the expiration date on package label.

OPERATIONAL INSTRUCTIONS

Alair Catheter Inspection and Preparation

1. The Alair System should only be used by a physician trained in bronchoscopy. These instructions do not explain bronchoscopic procedures.
2. Please read the Operator's Manual for the Alair RF Controller Model ATS 200 before beginning the procedure.
3. Visually inspect the package for damage before removing the Catheter from the package. Do not use the Catheter if the package is damaged or has been previously opened or torn.

4. Aseptically remove the Catheter from the package tray and inspect for any damage. The Catheter is packaged with the electrode array retracted within the protective, removable orange-colored Catheter tip sheath. Before use, remove the protective orange sheath. Inspect the Catheter for any damage such as broken or crushed areas of the Catheter, sharp or protruding edges at the distal tip, or any excessive bends or kinks in the Catheter shaft. Do not use the Catheter if any damage or irregularity is found. See Figure 4.

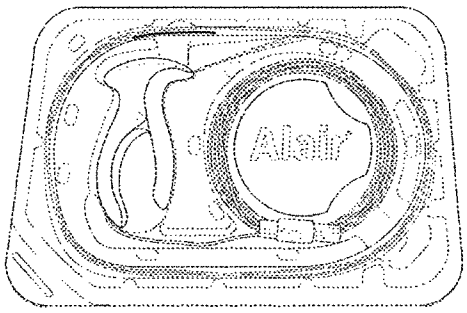


Figure 4. Alair™ Catheter in Tray

5. The distal portion of the Catheter shaft has marker bands that are spaced 5 mm apart to aid in the positioning of the Catheter electrode array. Do not use the Catheter if the marker bands are not visible. See Figure 5.

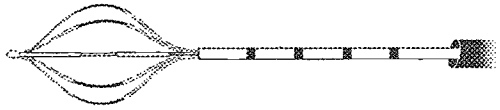


Figure 5. Alair Catheter with its four Marker Bands, spaced 5 mm apart

6. Hold the Catheter handle in the palm of your hand, with the thumb and forefinger just below the Alair logo. Then, squeeze the forward handle back towards the back handle, ensuring that the electrode array expands properly. Verify that the electrode array opens fully and evenly. See Figure 6.

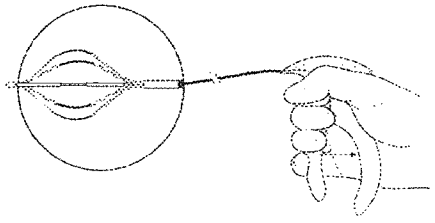


Figure 6: Alair Catheter Electrode Array Expanded

7. Relax the electrode array by releasing the front handle. See Figure 7. Do not use the Catheter if the electrode array does not expand or relax properly.

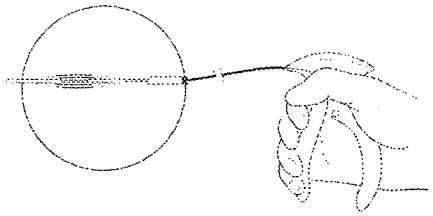


Figure 7: Alair Catheter Electrode Array Relaxed

Alair Bronchial Thermoplasty System Set-up and Operation

The Alair Catheter is intended to be used in conjunction with the Alair Controller. Please read the Alair RF Controller Model ATS 200 Operator's Manual before using the Alair System.

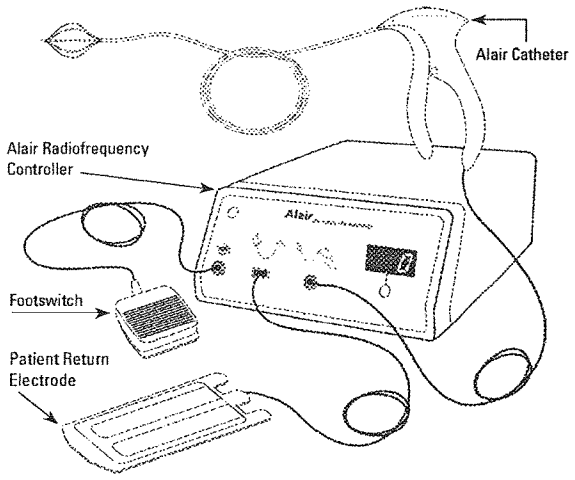


Figure 8: Alair RF Controller Model ATS 200 set up

Consult the Alair RF Controller Model ATS 200 Operator's Manual for specific instructions on:

- Controller Installation;
- Controller Power-Up;
- Connection of Components and Accessories;
- Controller Modes;
- Periodic Maintenance and Repair;
- Troubleshooting; and
- Technical Specifications.

Patient Preparation

1. Administer prophylactic prednisone or equivalent at a dosage of 50 mg/day for the 3 days before the procedure, the day of the procedure and the day after the procedure to minimize post procedure inflammation.

2. Pre-procedure spirometry: On the day of procedure, perform a post-bronchodilator (BD) FEV_1 to assess patient stability pre and post procedure. Pre-procedure FEV_1 value should be greater than or equal to 85% of normal value.
3. Verify the patient remains a good candidate for bronchoscopy under moderate sedation prior to initiation of the procedure (Mayse et al 2007)[5]. Postpone the procedure if any of the following conditions apply:
   - Prescribed prednisone was not taken on the 3 days before bronchoscopy.
   - SpO_2 is less than 90% on room air.
   - Increase in asthma symptoms in last 48 hours requiring more than 4 puffs/day on average of rescue bronchodilator over pretreatment usage.
   - Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days.
   - Active respiratory infection, active allergic sinusitis, or other clinical instability.
   - Physician feels for any reason the procedure should be postponed.
4. Prepare the patient for bronchoscopy. Administration of an antisialogogue (glycopyrrolate or atropine) is recommended to reduce airway secretions during procedure to improve visibility. Follow patient management protocols according to staffing, training, and individual institution-specific policies and guidelines for bronchoscopy.
5. Place the patient return electrode securely on the patient in accordance with manufacturer's instructions.
6. Introduce the flexible bronchoscope through the nose or mouth as appropriate. See Figure 9 below.

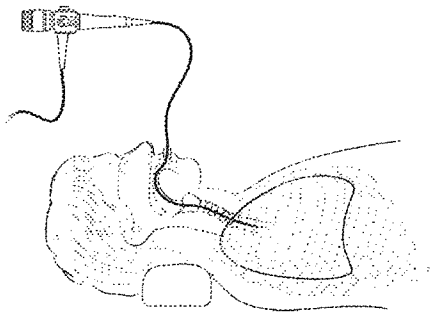


Figure 9: Bronchoscope navigation into patient's airways

7. Navigate the bronchoscope to the targeted site and position the bronchoscope so that the targeted site is in bronchoscopic view.

Alair™ Catheter Use

1. Before inserting the Catheter into the bronchoscope, ensure the Catheter is connected, the Controller is set up properly, and the electrode array is relaxed.
2. Advance the Catheter into the bronchoscope working channel being careful not to kink the Catheter shaft. Kinking of the Catheter shaft could result in failure of the Catheter electrode array to open fully in tortuous anatomy. See PRECAUTIONS.
3. Avoid deflecting the bronchoscope while the electrode array is within the bend of the bronchoscope's working channel as this could result in damage to the Catheter and failure of the Catheter to operate properly. See PRECAUTIONS.
4. Advance the Catheter through the bronchoscope until the distal tip of the Catheter shaft is in bronchoscopic view. If the device encounters significant resistance during insertion, do not force it. In especially tortuous anatomy it may be necessary to relax the bronchoscope's deflection mechanism until the device passes smoothly. See Figure 10 below.

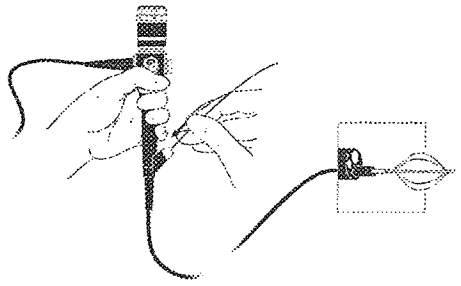


Figure 10: Alair Catheter introduced through working channel of bronchoscope

5. Advance the Catheter to the targeted site under bronchoscopic vision. Do not advance the Catheter into bronchi in which the Catheter cannot be seen under bronchoscopic vision. Advancing the Catheter under such conditions may result in pneumothorax, pneumomediastinum or other harm or injury to the patient. See WARNINGS.
6. Do not treat the right middle lobe because of the potential susceptibility of the right middle lobe to transient obstruction as a result of inflammation or edema due to certain anatomical characteristics. The narrow diameter of the lobar bronchus and acute take-off angle may create poor conditions of drainage that may cause patient harm or injury such as atelectasis or difficulty in re-inflation (Right Middle Lobe Syndrome). See WARNINGS.
7. Do not reposition the bronchoscope with the Catheter advanced beyond the distal end of the bronchoscope as this may result in harm or injury to the patient. See WARNINGS.
8. Once at the targeted site, squeeze the handle together to expand the electrode array partially so that the electrodes are close to or just touching the targeted site. With the electrode array partially expanded, adjust the axial position of the electrodes in the airway to position the active electrodes (exposed 5 mm center region of the array electrodes) as desired. Expand the array until all four electrodes firmly contact the airway wall. *Do not over-expand the electrode array* as this may cause one or more of electrodes to deploy inward or 'invert'. In most cases, contact with the airway wall will NOT require the Catheter handle to be squeezed completely. If an electrode inverts, relax the electrode array and then re-expand the array in a large, straight airway, confirming proper deployment before returning to the area being treated.
9. Proper contact of the electrodes with the airway wall should be confirmed visually. See Figure 11.

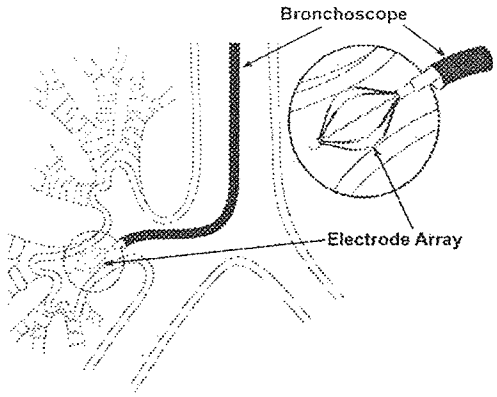


Figure 11: Alair™ Catheter in the Airway

10. Before delivering RF energy, make certain that all electrodes are in contact with the airway wall. See PRECAUTIONS.
11. Deliver RF energy to the targeted region by pressing and releasing the footswitch once. The Controller will deliver energy automatically according to preset parameters for time, energy, power, and temperature.
12. To manually terminate RF energy delivery, if necessary, press and release the footswitch again.

Note: The Controller will automatically shut off the RF energy if it detects atypical energy delivery or temperature response.

13. The Controller is programmed to alert the user with both audible and visual cues if re-deployment of the electrode array or replacement of the Catheter is required. Please refer to the Alair RF Controller Model ATS 200 Operator's Manual for more detailed instructions on these audible sounds and light displays.

Note: If RF energy delivery ends prematurely, it may be necessary to re-deploy the electrode array and begin RF energy delivery again. If the problem persists, replace the Catheter.

14. Reposition the Catheter and repeat the steps above making 5 mm proximally placed contiguous treatments. The Catheter's marker bands are spaced 5 mm apart to assist with contiguous placement. See Figure 12.

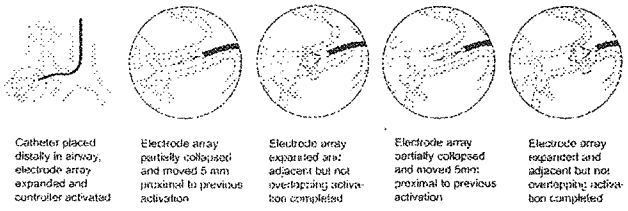


Figure 12: Contiguous Placement and Activation

15. It may be necessary to clean the electrode array if accumulated material on the array impairs visibility. To clean the electrode array follow these steps:
    - Remove the Catheter from the bronchoscope.
    - Expand the electrode array and vigorously swish the electrode array in a sterile container filled with ROOM TEMPERATURE saline.
    - DO NOT CLEAN THE ARRAY WITH COLD SALINE as this may trigger the Catheter failure alarm.
    - If further cleaning is necessary, wipe the array gently using a cotton swab or gauze.
16. Once the procedure is complete, relax the Catheter handle to relax the electrode array before removing the Catheter from the bronchoscope or before withdrawing the Catheter into the bronchoscope for airway navigation. To manipulate the bronchoscope with the Catheter in the working channel, withdraw the Catheter approximately 10 cm into the bronchoscope so the electrode array is proximal to the bend in the distal tip of the bronchoscope.
17. Once the treatment is complete, remove the Catheter from the bronchoscope. Disconnect the Catheter from the Controller, and dispose of the used Catheter per your institution's biohazard procedures. Remove the return electrode from the patient. Disconnect the patient return electrode from the Controller, and dispose of the patient return electrode per your institution's biohazard procedures.

Post Procedure Care

1. Follow appropriate institutional guidelines for post procedure care. It is recommended that patients should be carefully monitored and discharged only after they are deemed to be stable and have adequate (comparable to pre-procedure) lung function, mental status, and are able to adequately take liquids.
2. Recommended post procedure assessments are based on the criteria that were used in clinical trials of bronchial thermoplasty (Mayse et al 2007) and include:
    - 2 to 4 hour recovery/monitoring period following each procedure
    - Spirometry, breath sounds, and vital signs (heart rate, blood pressure, temperature, respiratory rate, pulse oximetry) before discharge
    - Discharge if post bronchodilator FEV_1 is within 80% of the pre procedure value and patient is feeling well
    - Verify patient has gag reflex and is able to take liquids
    - Remind patient to take prophylactic prednisone or equivalent the day following bronchoscopy
    - Caution patient about the potential adverse events that they might experience including hemoptysis, fever, cough, and worsening of asthma symptoms. Patients should be advised to consult their physician if they experience any of these adverse events, or asthma symptoms that are not controlled by their reliever medications.
    - Contact patient via phone calls at 1, 2 and 7 days to assess post procedure status
    - Office visit at 2 to 3 weeks to assess clinical stability and schedule subsequent bronchial thermoplasty procedures as appropriate

MAINTENANCE AND TROUBLESHOOTING

- If mucus builds up in the airways and obscures visualization, remove the Catheter from the bronchoscope, provide irrigation with sterile saline, and suction the resulting fluid from the airways.
- If the Catheter handle alarm (red light) appears on the Controller front panel the Catheter should be replaced. The only exception to this instruction occurs if the Catheter electrode array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling) the electrode array should be returned to room temperature and the Catheter connector should be unplugged and re-connected to the Controller. If the Catheter handle alarm persists, replace the Catheter and continue with the bronchial thermoplasty procedure.
- If the electrode array does not expand or relax properly, remove the Catheter from the bronchoscope and squeeze and relax the Catheter handle to visually confirm that the electrode array is functioning properly. If it is not functioning properly, replace the Catheter and continue with the bronchial thermoplasty procedure.
- If you are alerted to auditory or visual cues from the Controller, consult the Alair™ Bronchial Thermoplasty RF Controller Model ATS 200 Operator's Manual for operating and troubleshooting guidelines for the Controller.
- If an electrode inverts, relax the electrode array and then re-expand the array in a large, straight airway, confirming proper deployment before returning to the area being treated. In most cases, contact with the airway wall will NOT require the Catheter handle to be squeezed completely.

REFERENCES

1 Danek CJ, Lombard CM, Dungworth DL, Cox PG, Miller JD, Biggs MJ, Keast TM, Loomas BE, Wizeman WJ, Hogg JC, Leff AR. Reduction in airway hyperresponsiveness to methacholine by the application of RF energy in dogs. J Appl Physiol. 2004, 97(5):1946-53.

2 Brown RH, Wizeman W, Danek C, Mitzner W. Effect of bronchial thermoplasty on airway distensibility. Eur Respir J. 2005 Aug;26(2):277-82.

3 Mayse ML, Laviolette M, Rubin AS, Lampron N, Simoff M, Duhamel D, Musani, AI, Yung RC, Mehta AC. Clinical Pearls for Bronchial Thermoplasty. J Bronchol. 2007, 14:115-123.

NO IMPLIED LICENSE

The purchase of the Alair Catheter does not grant a license, either expressly, by implication, estoppel or otherwise under any Boston Scientific patent right or patent covering or relating to any method or process in which the Alair Catheter might be used. An implied license only exists for the Alair Catheter used in conjunction with the Alair ATS 200 Controller. Nothing herein shall be construed as right or license to (a) make, use, sell, offer to sell, import, lease or distribute the Alair Catheter with a non-Alair controller or (b) sell or offer to sell the Alair Catheter to customers that plan to make, have made, use, sell, offer to sell, import, lease or distribute the Alair Catheter with a non-Alair controller.

WARRANTY

Catheter - Warranty

Boston Scientific Corporation (BSC) warrants until the expiration marked on each instrument that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control may directly affect the instrument and the results obtained from its use. BSC shall replace any instrument that BSC determines was defective at the time of shipment if notice thereof is received before the expiration marked on the instrument. BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized; use by a non-qualified physician; use contrary to documentation; use with a non-Alair controller.**

Catalog Number


Consult instructions for use


Contents


Legal Manufacturer

Lot

Product Number


Recyclable Package


Use By


For single use only. Do not reuse.


Do Not Resterilize


Do not use if package is damaged.


Separate Collection

Sterilized using irradiation.

Minimum Required Working Channel

For prescription use only


Caution

Boston Scientific (Master Brand DFU Template 8in x 8in Global, 90108041AL), DFU, MB, Alair Catheter, Canada/Mexico, 90723943-01C

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

2012-11

90723943-01

Black (K) ΔE ≤5.0

Boston Scientific

ALAIR™

Bronchial Thermoplasty Radiofrequency Controller

Model ATS 200

Operator's Manual **3**

TABLE OF CONTENTS

ALAIR™

Bronchial Thermoplasty Radiofrequency Controller

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

FOR PROFESSIONAL USE ONLY

The Alair Radiofrequency Controller must be used by a physician who has training and experience in performing bronchoscopic procedures.

ALAIR BRONCHIAL THERMOPLASTY SYSTEM DESCRIPTION

This Operator's Manual provides instructions for using the Alair Radiofrequency (RF) Controller Model ATS 200. The Alair RF Controller Model ATS 200 is intended to be used with the Alair Catheter. The Alair RF Controller is designed to provide controlled delivery of radiofrequency energy to the Alair Catheter.

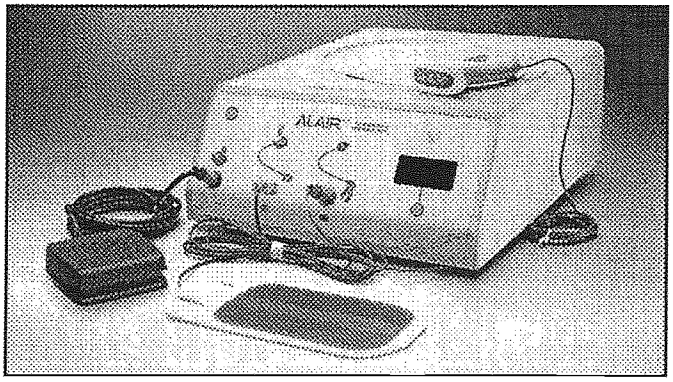


Figure 1. The Alair Bronchial Thermoplasty System

The Alair Bronchial Thermoplasty System ("Alair System"), manufactured by Boston Scientific Corporation (BSC), consists of the Alair Controller System and the Alair Catheter, as described below:

Alair Controller System

Alair Radiofrequency (RF) Controller: The Alair RF Controller Model ATS 200 ("Controller") is designed to provide controlled delivery of RF energy to the Alair Catheter. Energy from the Controller is delivered to the Catheter through the electrical cable attached to the proximal end of the Catheter handle. Actual power delivered is automatically modulated by the Controller based on temperature control algorithms. The Controller delivers low-power, temperature-controlled RF energy to the airway at a predetermined temperature setting for a predetermined time period. The Controller incorporates hardware and software features that limit current, voltage, power, energy, time and temperature during each application of RF energy. The Controller is not intended to come in contact with the patient and therefore is not provided as a sterile device.

Footswitch: The Controller is used with a footswitch that allows the operator to start and stop the delivery of RF energy. The Controller is designed to be used with the compatible footswitch provided by BSC. The footswitch is not intended to come into contact with the patient and therefore is not provided as a sterile device.

Patient Return Electrode: The Controller is designed to be used with a gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. The patient return electrode is used to complete the return path for the electrical current. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs). Examples of acceptable patient return electrodes include Valleylab™ E7506 and ConMed™ 51-7310. Follow the directions for use (DFU) packaged with the patient return electrode.

Alair Catheter

The Alair Catheter Model ATS 2-5 ("Catheter") is provided sterile and is a SINGLE-USE ONLY, disposable device. The Catheter delivers energy from the Controller to the desired site in the airway and relays temperature feedback to the Controller. The Alair Catheter Model ATS 2-5 is designed to be used with the Alair RF Controller Model ATS 200. For information on the preparation, use and other technical specifications, please refer to the Alair Catheter directions for use (DFU) that is supplied with Model ATS 2-5.

Contents

One (1) Alair Radiofrequency Controller Model ATS 200
One (1) Alair Radiofrequency Controller Accessory Kit Model ATS 201
- One (1) Footswitch
- One (1) Power cord

INDICATION FOR USE

The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists.

MECHANISM OF ACTION

Airway smooth muscle (ASM) consists of muscle tissue within the airway walls in the lung. Contraction of the ASM is a main cause of airway constriction that leads to difficulty in breathing during asthma attacks. Severe asthma patients also experience an increase in ASM mass. This increase, together with inflammation of the airways, combines to thicken airway walls, which decreases the inside diameter of the airways when the ASM contracts. The resulting decrease in airway diameter causes increased resistance to airflow and further contributes to difficulty in breathing during asthma attacks.

The Alair System is used to deliver thermal energy to the airway wall, to heat the tissue in a controlled manner in order to reduce ASM mass. Bronchial thermoplasty is intended to reduce, debulk, or partially eliminate smooth muscle tissue. In preclinical studies (Danek et al. 2004[1], Brown et al. 2005[2]), the reduction of ASM has been shown to decrease the ability of the airways to constrict/contract, reduce resistance to airflow and responsiveness of the airway, and increase the resting diameter of the airway.

CONTRAINDICATIONS

Patients with the following conditions should not be treated:

- Presence of a pacemaker, internal defibrillator, or other implantable electronic devices,

- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines,
- Patients previously treated with the Alair™ System should not be retreated in the same area(s). No clinical data are available studying the safety and/or effectiveness of repeat treatments.

Patients should not be treated while the following conditions are present:

- Active respiratory infection,
- Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days,
- Known coagulopathy,
- As with other bronchoscopic procedures, patients should stop taking anticoagulants, antiplatelet agents, aspirin and NSAIDS before the procedure with physician guidance.

WARNINGS ⚠

Read this operator's manual in conjunction with the Alair Catheter Model ATS 2-5 directions for use before using the Alair Bronchial Thermoplasty System. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient.

Controller/RF Energy Warnings:

1 Do not use RF energy in the presence of flammable anesthesia or other flammable gases, flammable liquids (such as skin prepping agents and tinctures), or flammable objects. Non-flammable agents should be used for cleaning and disinfecting whenever possible. Flammable agents used for cleaning, disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of RF energy.

2 While using this device in oxygen-enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents, follow appropriate guidelines for reducing the risk of surgical fires.

3 Do not cut a patient return electrode to make it smaller as reducing the size of the patient return electrode may result in patient burns due to high current density.

4 Do not wrap the power cord, patient return electrode cord, or Catheter cable around metal objects as hazardous currents may be induced leading to harm or injury (e.g. shock) to the patient or medical personnel, or fire.

5 While using this device, the patient should not be allowed to come into contact with grounded metal objects as harm or injury to the patient may result. Antistatic sheeting is recommended to prevent the patient from coming into contact with metal parts which are connected to earth or which have an appreciable capacitance to earth.

6 Skin-to-skin contact (e.g. contact between the arms and body of the patient) should be avoided by inserting dry gauze.

7 The electrical cord supplied for the Controller must be connected to a properly grounded receptacle. Do not use extension cords or adapters.

8 Exposing the Controller to liquids may result in harm or injury (e.g. electrical shock) to the patient and/or user or damage to the Controller.

9 Failure of the Controller may result in an unintended increase of output power.

10 When the Controller and physiological monitoring equipment are used simultaneously on the patient, any monitoring electrodes should be placed as far as possible from the patient return electrode. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.

11 The Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller should be observed to verify normal operation in the configuration in which it will be used. When RF energy is delivered, conducted and radiated electrical fields may interfere with other electrical medical equipment stacked with or placed adjacent to the Controller.

12 Do not open the Controller enclosure or tamper with the Controller in any way. Harm or injury (e.g. electrical shock) or damage to the Controller may result. Contact BSC for repair/replacement.

13 Use of the Controller with a non-Alair catheter may result in harm or injury to the patient and/or operator, or may result in product malfunction.

14 To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

15 The use of RF energy can produce unintended neuromuscular stimulation. Appropriate precautions, including continuous monitoring of the patient during treatment, should be taken to minimize the risk of patient injury.

16 No modification of this equipment is allowed.

Catheter Warnings:

1 Prior to performing the procedure, ensure appropriate training, equipment, medications and staff are in place to handle any potential bronchoscopic, respiratory or anesthesia related emergencies. The Alair System should only be used in a fully equipped bronchoscopy suite with access to full resuscitation equipment to handle hemoptysis, pneumothorax, and other respiratory complications including acute exacerbation of asthma and respiratory failure requiring intubation.

2 Do not deliver energy if the Catheter's electrode array is in contact with a metal object. This may result in harm or injury to the patient and/or operator.

3 Do not advance the Catheter within the bronchoscope if significant resistance is felt, as this may result in harm or injury to the patient and/or cause damage to the Catheter and/or bronchoscope.

4 Do not advance the Catheter into bronchi in which the Catheter cannot be seen under bronchoscopic vision. Advancing the Catheter beyond this region may cause patient harm or injury such as pneumothorax or pneumomediastinum.

5 Do not reposition the bronchoscope with the Catheter advanced beyond the distal end of the bronchoscope as this may result in patient harm or injury.

6 Use of the Alair Catheter with a non-Alair controller may result in harm or injury to the patient and/or operator, or may result in product malfunction.

7 Do not treat the right middle lobe because of the potential susceptibility of the right middle lobe to transient obstruction as a result of inflammation or edema due to certain anatomical characteristics. The narrow diameter of the lobar bronchus and acute take-off angle may create poor conditions of drainage that may cause patient harm or injury such as atelectasis or difficulty in re-inflation (Right Middle Lobe Syndrome).

8 No modification of this equipment is allowed.

PRECAUTIONS ⚠

Controller/RF Energy Precautions:

1 Alair System components and accessories need to be rated for at least the maximum peak output voltage as specified in the Technical Specifications

section of this manual. The Catheter designed for use with this Controller is rated for the maximum peak output voltage as specified in the Technical Specifications section of this manual.

2 Use a Valleylab™ E7506, ConMed™ 51-7310, or a similar gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs).

3 Verify that all oxygen circuit connections are leak-free before and during the use of RF energy. Verify that the endotracheal tube (if used) is leak-free, and that the cuff is properly sealed to prevent oxygen leaks.

4 The RF delivery tones and indicator lights on the front panel are important safety features. Do not obstruct your view of the Controller's front panel.

5 Proper placement of a patient return electrode is required for the use of this device. Ensure the entire patient return electrode is securely placed on a suitably prepared area on the patient in accordance with the manufacturer's instructions. Check the patient return electrode before and periodically during system use to ensure that it is in firm contact with the skin, especially whenever the patient is repositioned.

6 The Catheter cable should be positioned in such a way that contact with the patient return electrode cable or other wires is avoided.

7 The Alair™ System needs special precautions regarding Electromagnetic Compatibility ("EMC"). Portable and mobile communications devices can affect proper operation of the Alair System. The Alair System should be installed and used in accordance with the EMC information provided in this Operator's Manual.

8 The use of components or accessories other than an Alair Catheter, or as suggested by BSC, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Controller.

9 Follow local governing ordinances and your institution's biohazard procedures regarding disposal of the Alair Controller, Footswitch, and Power Cords.

Catheter Precautions:

1 The Alair Catheter is provided sterile and is SINGLE USE ONLY. Do not use the Catheter if the package is opened, torn, or damaged. Use of a Catheter from damaged packaging may result in patient harm or injury. **Do not re-sterilize, reprocess or reuse** the Catheter, as this may result in patient harm or injury, transmittal of infectious disease or product malfunction.

2 Do not use the Catheter if it comes in contact with a surface that is not aseptic (e.g. floor). This may result in patient infection.

3 Do not use the Catheter if it is damaged or irregular. Use of a damaged or irregular Catheter may result in patient harm or injury.

4 Do not use the Catheter if the marker bands are not visible.

5 Use care when handling the Catheter to avoid kinking the Catheter shaft.

6 Avoid deflecting the bronchoscope while the electrode array is within the bend of the bronchoscope's working channel as this may result in damage to the Catheter and failure of the Catheter to operate properly.

7 Before inserting or removing the Catheter from the bronchoscope, ensure the electrode array is relaxed. Do not use the Catheter if the electrode array does not expand or relax properly.

8 Before delivering energy, make certain that all electrodes are in contact with the airway wall.

9 Caution should be taken in patients with the following conditions due to a potential increased risk of adverse events that may be associated with the procedure. Patients with these conditions were not studied in the pivotal trial and the safety of Alair treatment for such patients has not been determined:

- Post-bronchodilator $FEV_1 < 65\%$ predicted.
- Other respiratory diseases including emphysema, vocal cord dysfunction, mechanical upper airway obstruction, cystic fibrosis or uncontrolled obstructive sleep apnea.
- Use of short-acting bronchodilator in excess of 12 puffs per day within 48 hours of bronchoscopy (excluding prophylactic use for exercise).
- Use of oral corticosteroids in excess of 10 milligrams per day for asthma.
- Increased risk for adverse events associated with bronchoscopy or anesthesia, such as pregnancy, insulin dependent diabetes, epilepsy or other significant co-morbidities, such as uncontrolled coronary artery disease, acute or chronic renal failure, and uncontrolled hypertension.
- Intubation for asthma, or ICU admission for asthma within the prior 24 months.
- Any of the following within the past 12 months:
  - i. 4 or more lower respiratory tract infections (LRTI)
  - ii. 3 or more hospitalizations for respiratory symptoms
  - iii. 4 or more OCS pulses for asthma exacerbation

10 The Alair System should only be used by clinicians who are experienced in bronchoscopy and have undergone adequate training with the device.

11 The Alair System should only be used in patients stable enough to undergo bronchoscopy in the judgment of their clinician.

12 Follow local governing ordinances and your institution's biohazard procedures regarding disposal of the Alair Catheter and patient return electrode.

CLINICAL STUDIES

Objectives

The pivotal study was a multi-center, randomized, double-blind, sham-controlled study to demonstrate the safety and effectiveness of the Alair System in a population of subjects with severe asthma.

Effectiveness Endpoints

The primary effectiveness endpoint was the difference between treatment (Alair) and control (Sham) groups in the change in the Asthma Quality of Life Questionnaire (AQLQ) score between baseline and the average of 6-, 9-, and 12-month follow-up visits (integrated AQLQ score). Other endpoints included: rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. In addition, several safety endpoints were considered for effectiveness; these endpoints included rates of asthma (multiple symptoms)* adverse events, Unscheduled Physician Office visits for respiratory symptoms, Emergency Room visits for respiratory symptoms, and Hospitalizations for respiratory symptoms.

* "Asthma (multiple symptoms)" is defined as occurrence or worsening of shortness of breath, wheeze, cough, productive cough, or some combination of these.

Methods

This was a multicenter, randomized (2 Alair, 1 Sham), double-blind, sham-controlled clinical trial comparing the effects of treatment with the Alair System to a Sham treatment in subjects that were optimized to conventional therapy of inhaled corticosteroids (ICS) and long-acting β_2-agonists (LABA). All subjects included in

the Study were taking ICS (> 1000 µg beclomethasone or equivalent per day) and LABA (≥ 100 µg salmeterol or equivalent per day), and were still symptomatic.

Subjects in the Alair and Sham groups were administered the Alair treatment and Sham bronchoscopies, respectively, by an unblinded bronchoscopy team in 3 separate bronchoscopy sessions. Each bronchoscopy session was separated by at least 3 weeks. All bronchoscopy sessions were administered under local anesthesia with sedation. Subjects had follow-up visits with blinded asthma assessment teams at 6-weeks, 12-weeks, 6-months, 9-months, and 12-months after the final bronchoscopy session.

All subjects were prescribed to take 50 mg of oral prednisone or prednisolone (or equivalent) each day for 5 days covering the 3 days before the bronchoscopy session, the day of the bronchoscopy session, and the day after the bronchoscopy session (prophylactic indication).

Statistical Plan

Primary and secondary endpoints, as well as adverse events were analyzed using Bayesian statistics. The Posterior Probability of Superiority was calculated for the primary and secondary endpoints, as well as safety outcomes.

Patient Population

Enrollment was limited to patients with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA. Subjects may have been taking up to 10 milligrams of oral corticosteroids per day. Study subjects were required to meet the following patient selection criteria:

Key Entry Criteria

Inclusion

1. Adult; age 18-65 years.
2. Asthma requiring regular maintenance medication that includes inhaled corticosteroids (greater than 1000 µg beclomethasone per day or equivalent) and long-acting β_2-agonists (at least 100 µg salmeterol per day or equivalent), with or without other asthma medications. Oral corticosteroids at a dosage of up to, but not greater than 10 mg per day, or 20 mg every other day are acceptable.
3. Asthma Quality of Life Questionnaire Score during the Baseline Phase of 6.25 or less.
4. Pre-bronchodilator forced expiratory volume in one second ≥ 60% predicted (after patients stabilized on inhaled corticosteroids and long-acting β_2-agonists during the Baseline Phase).
5. Non-smoker x 1 year or greater (if former smoker, less than 10 pack years total smoking history).

Exclusion

1. Post-bronchodilator FEV_1 < 65% predicted.
2. Three or more hospitalizations for exacerbations of asthma in the previous year; OR a history of life-threatening asthma, defined by past intubations for asthma, or intensive care unit admission for asthma within the prior 24 months.
3. History of recurrent lower respiratory tract infection requiring antibiotics (more than 3 in the past 12-Months).
4. History of recurrent oral steroid use for asthma (4 or more pulses of oral steroids in the past 12-Months).

Demographics

A total of 297 subjects between the ages of 18 and 65 were enrolled and randomized (2 Alair: 1 Sham) in this study. One hundred and ninety (190) subjects received the Alair treatment and 98 subjects received the Sham control treatment (Intent-to-Treat population). The Sham procedure was identical to the Alair procedure except that no energy was delivered through the Catheter.

There were no statistical differences in demographic measures between the Alair and Sham groups. Subject demographics are described in Table 1.

	Alair (n=190)	Sham (n=98)
Age (years) (Mean ± SD)	41 ± 12	41 ± 12
Gender		
Male	81 (43%)	38 (39%)
Female	109 (57%)	60 (61%)
Race/Ethnicity		
Caucasian	151 (80%)	72 (74%)
African American / Black	19 (10%)	15 (15%)
Hispanic	6 (3%)	4 (4%)
Asian	4 (2%)	1 (1%)
Other	10 (5%)	6 (6%)
Height (cm) (Mean ± SD)	167 ± 9	167 ± 10
Weight (kg) (Mean ± SD)	82 ± 18	82 ± 20

Table 1: Subject Demographics (Intent-to-Treat Population)

Effectiveness Results

Effectiveness analyses were performed for both the Intent-to-Treat (ITT) population and Per-Protocol (PP) population. The ITT population consisted of all randomized subjects who have been administered at least one bronchoscopy. The PP population excluded all subjects in the ITT population who met any of the following criteria:

- Have taken any interfering concomitant medications.
- Have undergone other interfering treatments.
- Did not attend one of the 6-, 9-, 12-month visits, with the exception of a discontinuation from the Study due to an adverse event related to Study treatment.
- Had missed one or more bronchoscopy procedures.

Effectiveness Endpoints

Although the clinical study was powered only for the primary effectiveness endpoint (see below), several effectiveness endpoints and safety endpoints that could also be considered effectiveness endpoints demonstrated clinically meaningful differences in favor of the Alair group compared to the Sham group. The effectiveness endpoints were rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. The safety endpoints considered for effectiveness were rates of asthma, emergency room visits for respiratory symptoms, and hospitalization rates for respiratory symptoms.

Steroid Exacerbations[a] (Severe Exacerbations Requiring Systemic Corticosteroids) (ITT Population)

During the Post-Treatment Phase, the severe exacerbation rate for the Steroid Exacerbations was 0.48 exacerbations/subject/year in the Alair group and 0.70 exacerbations/subject/year in the Sham group [95% CI (Sham - Alair): -0.031, 0.520]. During the Post-Treatment Phase, the proportion of subjects experiencing Steroid Exacerbations was 26% in the Alair group and 40% in the Sham group [95% CI (Sham - Alair): 2.1%, 25.1%].

Steroid Exacerbation rates (annualized rate) and proportion of patients experiencing Severe Exacerbations for the Post-Treatment Phase are presented graphically in Figure 2.

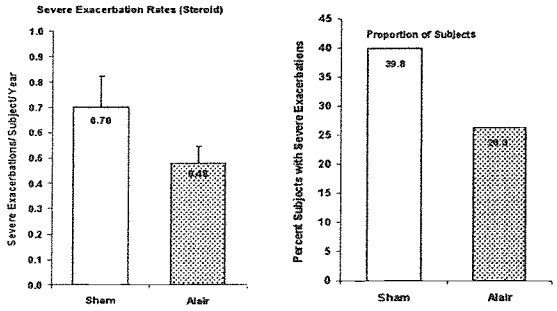


Figure 2: Severe Exacerbations during the Post-Treatment Phase

[a] **Steroid Exacerbations** = Exacerbations treated with oral or intravenous corticosteroids, OR a doubling of the baseline inhaled corticosteroid dose for at least 3 days, OR any temporary increase in the dosage of oral corticosteroids for a subject taking maintenance oral corticosteroids at Study entry.

Annualized rates of exacerbations per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit.

Days Lost from Work, School, or Other Daily Activities due to Asthma Symptoms (ITT Population)

During the Post-Treatment Phase, subjects in the Alair group lost an average of 1.3 days/year/subject from work, school, or other daily activities due to asthma symptoms, compared to the Sham group that lost 3.9 days/year/subject (annualized rates per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit) [95% CI (Sham - Alair): 0.425, 6.397].

Safety Endpoints that Demonstrated Effectiveness

Measures such as Emergency Room visits and Hospitalizations for respiratory symptoms are generally considered to be important measures of safety, especially if an intervention results in an increase in the rate of one or more of these events. During longer-term follow-up (> 6 weeks after the last Alair treatment), there was a reduction in asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): -0.01, 0.001], Emergency Room visits for respiratory symptoms [95% CI (Sham - Alair): 0.11, 0.83], and Hospitalizations for respiratory symptoms (event rate per group) [95% CI (Sham - Alair): 0.025, 0.172], presented graphically in Figure 3.

There was a reduction in the proportion of subjects having asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): 4.0%, 27.3%], and in the proportion of subjects having Emergency Room visits for respiratory symptoms in the Alair group (3.7% in the Alair group compared to 15.3% in the Sham group) [95% CI (Sham - Alair): 4.6%, 19.7%].

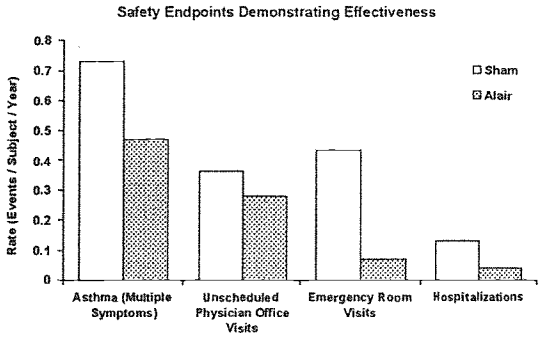


Figure 3: Safety Endpoints demonstrating Effectiveness (ITT Population)

Primary Effectiveness Endpoint – Integrated AQLQ Score

The difference between the Alair and Sham groups in the average change in AQLQ score from Baseline at the 6-, 9-, and 12-month follow-up visits was 0.210 [95% CI (Alair - Sham): -0.025, 0.445]. The pre-specified Posterior Probability of Superiority for the difference between the groups was 96.4%. For the ITT population, the difference between the groups had a Posterior Probability of Superiority of 96.0%, and for the PP population, the difference between the groups had a Posterior Probability of Superiority of 97.9%, demonstrating an improvement in the Asthma Quality of Life in the Alair group compared to Sham.

The results for the change from Baseline of the Integrated AQLQ score for the Intent-to-Treat and Per Protocol populations are summarized in Table 2.

Population	Difference Between Groups in Integrated AQLQ Score (Posterior Mean, 95% CI)	Posterior Probability of Superiority (%)
ITT (Intent-to-Treat) (Alair N=190, Sham N=98)	0.210 (-0.025, 0.445)	96.0
PP (Per Protocol) (Alair N=173, Sham N=95)	0.244 (0.009, 0.478)	97.9

Table 2: Primary Effectiveness Endpoint: Integrated AQLQ Score

ADVERSE EVENTS IN PIVOTAL STUDY

Patient Population

The Alair™ System was evaluated in a randomized, double-blind, sham-controlled, multi-center clinical study – the Asthma Intervention Research 2 (AIR2) Trial. A total of 297 subjects with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA were randomized – 196 subjects in the Alair group and 101 subjects in the Sham group. (See the Clinical Data section for key entry criteria.) The Sham procedure was identical to the Alair procedure except that no energy was delivered to the Catheter in the sham procedure.

Safety analyses were performed for the Intent-to-Treat (ITT) population (288 subjects) that consisted of all randomized subjects who have been administered at least one bronchoscopy.

Observed Adverse Events

The safety of the Alair™ System was assessed by comparing adverse event profiles of the Alair and Sham group subjects. Adverse event profiles are compared for the Treatment Phase (day of first bronchoscopy procedure to 6 weeks after the last bronchoscopy procedure) and Post-Treatment Phase (6 weeks after the last bronchoscopy to the 12 month follow-up visit).

Adverse events (whether considered procedure-related or not procedure related by the investigator) occurring with ≥ 3% incidence in the Alair group are presented for 288 patients in Table 3.

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Average duration of period (days)	84		322	
Ear, Nose, and Throat				
Upper respiratory tract infection	20	11	30	26
Nasopharyngitis	5	7	11	5
Throat irritation	5	12	1	3
Viral upper respiratory tract infection	4	2	6	7
Sinusitis	3	5	6	7
Acute Sinusitis	3	2	4	8
Pharyngolaryngeal pain	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
Lower Respiratory				
Asthma (Multiple Symptoms)	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Dyspnea	11	6	2	1
Chest discomfort	9	10	2	1
Lower respiratory tract infection	8	2	3	6
Productive cough	7	9	3	4
Atelectasis	5	0	0	0
Bronchitis	4	2	7	5
Hemoptysis	3	0	0	0
Neurology				
Headaches	14	9	5	3
Anxiety	4	0	1	2
Dyspepsia	4	2	2	4
Nausea	3	4	1	1
Non-site specific				
Influenza	4	2	4	12
Pyrexia (fever)	4	2	0	1
Other				
Back pain	5	6	3	5
Hypertension	3	2	3	3
Urinary tract infection	1	1	3	1

Table 3: Adverse Events with ≥ 3% Incidence (% of subjects) in the Alair Group

* Treatment phase represents adverse events reported between the first bronchoscopy and 6-weeks post last bronchoscopy.

** Post-Treatment phase represents adverse events reported between 6-weeks post last bronchoscopy and the 12 month visit.

Respiratory adverse events occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair group included abnormal breath sounds, acute bronchitis, bronchial obstruction, bronchospasm, discolored sputum (blood-tinged sputum), epistaxis, hypoxia, increased upper airway secretion, nasal congestion, operative hemorrhage, pneumonia, pulmonary congestion, rhinorrhea, viral lower respiratory tract infection, and viral pharyngitis.

Non-respiratory adverse events occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair group included abdominal pain, acne, allergic dermatitis, arthralgia, back injury, candidiasis, conjunctivitis, cystitis, depression, diarrhea, dizziness, fatigue, food poisoning, gastritis, gastroenteritis, gastroesophageal reflux disease, gastrointestinal infection, heart palpitations, herpes simplex, hiccups, hyperglycemia, hypersensitivity, hypotension, injury, insomnia, intervertebral disc protrusion, joint sprain, ligament rupture, migraine, muscle strain, musculoskeletal pain, nephrolithiasis, oral candidiasis, pain in extremity, peripheral edema, procedural pain, rash, skin laceration, tendonitis, tonsillitis, tooth abscess, tooth extraction, tooth infection, toothache, tremor, viral tonsillitis, and vomiting.

There may be other risks associated with the procedure and attendant anesthesia and medications. Please consult the manufacturers' directions for use for the equipment and medications used in association with the bronchial thermoplasty procedure for relevant indications, warnings, precautions, and adverse events.

During the Treatment Phase in the AIR2 Trial, there was a transient increase in respiratory adverse events, including asthma (multiple symptoms), upper respiratory tract infection, atelectasis, lower respiratory tract infection, wheezing, hemoptysis, and anxiety in the Alair group compared to the Sham group. There was a lower incidence of throat irritation in the Alair group compared to the Sham group. There were 7 instances of hemoptysis defined as > 5.0 mL (1.3% of bronchoscopies) of

which 2 occurred on the day of the procedure, 2 occurred within 3 days, 2 occurred at 2 weeks, and one occurred on Day 31 after the procedure. The greatest amount of hemoptysis observed was a cumulative total of 150 mL that occurred over 5 days and was treated with bronchial artery embolization.

During the Treatment Phase (~12 weeks period), the rate of Unscheduled Physician Office visits (events / subject / 12 weeks) in the Alair group was 0.230 compared to 0.133 in the Sham group. The rate of Hospitalizations for respiratory symptoms (events / subject / 12 weeks) was 0.086 in the Alair group compared to 0.028 in the Sham group. The rate of Emergency Room visits for respiratory symptoms (events / subject / 12 weeks) was 0.062 in the Alair group compared to 0.075 in the Sham group.

During the Post-Treatment Phase in the AIR2 Trial, there was a lower incidence of respiratory symptoms in the Alair group compared to the Sham group, including a 36% reduction in asthma (multiple symptoms) events and proportion of subjects with asthma (multiple symptoms) events. There was also a lower incidence of influenza, and a greater incidence of nasopharyngitis, in the Alair group compared to the Sham group.

High Resolution Computed Tomography (HRCT) Results

In the 150 subjects (100 Alair group and 50 Sham group) assigned to HRCT scan examinations, at 1-year, there were no difference in signs of gas trapping or consolidation and there was no evidence of bronchiectasis. A difference was seen in bronchial wall thickening without gas trapping which occurred only in the Sham subjects (4%).

Summary of Clinical Findings

Results from the clinical study which evaluated the effectiveness and safety of the Alair™ System in subjects with severe asthma demonstrated that Alair treatment resulted in clinically significant reductions in severe exacerbations that required systemic steroids, the percent of subjects experiencing the severe exacerbations, the number of Emergency Room visits for respiratory symptoms, the percent of subjects experiencing Emergency Room visits for respiratory symptoms, Hospitalizations for respiratory symptoms, and days lost from school/work/ other daily activities due to asthma symptoms. Although bronchial thermoplasty was associated with an increased rate of respiratory adverse events during the Treatment Phase (primarily related to asthma), in the Post-Treatment Phase, a smaller proportion of patients treated with bronchial thermoplasty experienced respiratory adverse events, including asthma (multiple symptoms).

INSTALLATION

Inspect the Controller for any signs of physical damage. If physical damage is found, do not use. Please contact BSC for repair/replacement.

Preparing the Alair Controller for Use

The Controller should be placed on a sturdy cart, table, or platform. Provide at least four to six inches of space around the sides and top of the Controller to allow adequate ventilation. It is normal for the top and rear panel to be warm under continuous use.

Power Cord

The Controller is intended for use with a Boston Scientific approved power cord. Do not use extension cords or adapters. The power cord is to be used to isolate the Alair Controller from the supply mains. Do not position the Alair Controller so that it is difficult to disconnect.

Proper Grounding

To ensure patient safety, the Controller must be properly grounded. The ground wire in the power cord is connected to the Controller chassis and ensures that no dangerous currents will flow from the Controller chassis in the event of internal electrical failure.

Routine Inspections and Maintenance

The power cord assembly should be periodically checked for damage to the insulation or connectors. In the event that the Controller requires repair/replacement, please contact BSC. If needed, only your institution's biomedical engineering representatives should replace the Controller fuses. Routine maintenance and calibration of the Controller are not required.

Cleaning and Disinfecting Instructions

Disconnect the power cord before cleaning or disinfecting the unit. Use a mild non-abrasive detergent or cleaning/disinfecting solution and damp cloth to clean the Controller enclosure, front panel, and power cable. Do not allow fluids to enter the enclosure, power cable connections, or component/accessory connections. Do not attempt to clean the unit while it is plugged into an electrical outlet.

Note: Do not spray or pour liquid onto the Controller. Exposure of the Controller to liquids may result in electrical shock to the user or damage to the Controller.

Front Panel Indicators, Display, and Receptacles

A description of the front panel indicators, control buttons and their functions is given below. Please refer to Figure 4 for the location of each item on the front panel.

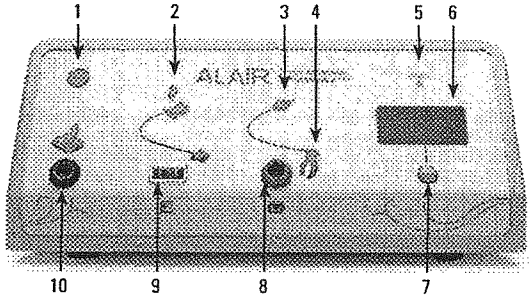
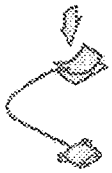
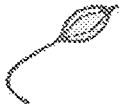
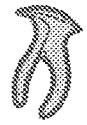
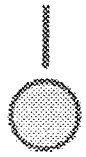
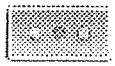


Figure 4. Alair Controller Front Panel

INDICATORS	
	**1. Status Indicator** – This indicator gives the user a signal about the overall readiness of the Alair System. When the Status Indicator light is *green* the Controller is in READY mode and able to deliver RF energy. When the Status Indicator light is *amber* the Controller is in STANDBY mode and is not capable of delivering RF energy. More detail on the Controller modes is provided below.
	**2. Patient Return Electrode Icon** – When the Patient Return Electrode Icon light is *amber* the user should ensure that the patient return electrode gel pad is correctly applied to the patient. After ensuring proper electrode placement, proceed by re-expanding the Catheter electrode array, taking care to ensure proper contact of all electrodes with the airway wall, and ensuring minimal movement of the electrode array during delivery of RF energy; then, continue.

INDICATORS (continued)	
	**3. Catheter Electrode Array Icon** – When the Catheter Electrode Array Icon light is *amber* the user should re-expand the Catheter electrode array, taking care to ensure proper placement and contact of all electrodes with the airway wall and ensuring minimal movement of the electrode array during delivery of RF energy; then, continue.
	**4. Catheter Handle Icon** – When the Catheter Handle Icon is flashing *red* the Catheter should be discarded and replaced with a new Catheter. The only exception to this instruction occurs if the Catheter array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling), the electrode array should be returned to room temperature and the catheter connector should be unplugged and re-connected to the Controller. If the Catheter Handle alarm persists, replace Catheter and continue with the bronchial thermoplasty procedure.
	**5. RF Energy Icon** – When the RF Energy Icon light is *blue* the Controller is delivering RF energy. This icon lights only while RF energy is being delivered.
DISPLAY	
	**6. Activation Counter Digital Display** – Displays the number of complete activations performed during device use.
	**7. Activation Counter Button** – When the counter button is depressed and released, the counter displays the number of incomplete activations for 5 seconds. When the counter button is depressed and held for 4 seconds, the complete and incomplete activation counters are reset to zero. ***Note:*** *The activation counter will not reset during the display of incomplete activations. Reset the activation counter only during the display of complete activations.*
RECEPTACLES	
	**8. Catheter Receptacle** – The *grey* receptacle accepts Catheter connectors and is keyed to ensure proper orientation. This connector is isolated from ground and AC mains to protect the patient from electrical hazards.
	**9. Patient Return Electrode Receptacle** – This receptacle accepts any standard, 2-pin patient return electrode connector. This connector is isolated from ground and AC mains to protect the patient from electrical hazards.
	**10. Footswitch Receptacle** – The *black* footswitch receptacle accepts the footswitch connector and is keyed to insure proper orientation. A single activation of the footswitch will turn the RF output ON if it was OFF, and turn the RF output OFF if it was ON.

Rear Panel Indicators and Functions

A description of the rear panel indicators and functions is given below. Please refer to Figure 5 for the location of each item on the rear panel.

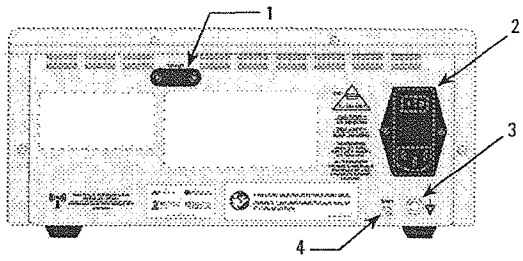


Figure 5. Alair™ Controller Rear Panel

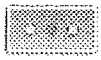
1. **Serial Communication Port** – For service by authorized personnel only. Not for use by user.
2. **Power Entry Module** – This module contains both the ON/OFF switch (I/O) and the power connection.
3. **Equipotentiality Connector** – Provides a means of securely linking the chassis of the Controller to the potential equalization system at the installation site.
4. **Program Memory Enable Screw** – For service by authorized personnel only. Not for use by user.

OPERATIONAL INSTRUCTIONS

Alair Controller Power-Up

1. Plug the Controller into a grounded receptacle. Do not use extension cords or adapters.
2. Turn the power on using the ON/OFF switch that is located on the Power Entry Module on the rear panel of the Controller **(see Figure 5 above)**. The Controller will perform a number of internal self-tests: a tone will sound and all indicators will light for approximately 1 second. Do not use the Controller if any of the indicators fails to light or this tone is not heard. In the event of malfunction, contact BSC for repair or replacement.
3. Once the self-test is completed, the Controller will enter STANDBY mode with the digital display showing zero [0] and the Status Indicator illuminated *amber* **(refer to Figure 4 above for the location of all controls and indicators).**
4. The Status Indicator light will transition from *amber* to *green* once all component and accessory connections have been made.
5. If the Controller goes directly into FAULT mode with all lights flashing upon start-up (see the Controller Modes section below for explanation of FAULT mode conditions), turn the Controller power switch OFF and ON again. If the Controller continues to enter the FAULT mode contact BSC for repair or replacement information.

Connection of Alair™ System Components and Accessories



1. Connect a suitable, 2-pin patient return electrode to the corresponding electrode receptacle on the front panel of the Controller following the manufacturer's DFU **(see illustration at left).** This receptacle has a patient return electrode icon directly above it. Place the patient return electrode securely on the patient in accordance with the patient return electrode manufacturer's instructions.

2. Connect the *black* footswitch cable connector supplied with the Controller to the matching *black* footswitch receptacle on the front panel of the Controller **(see illustration at left).** The appropriate receptacle has a footswitch icon directly above it. Ensure that the connector is securely attached to the Alair Controller before proceeding.

3. Connect the *grey* Catheter electrical cable to the matching *grey* Catheter receptacle on the Controller front panel **(see illustration at left).** The appropriate receptacle has a Catheter icon directly above it. Ensure that the connector is securely attached to the Alair Controller before proceeding.

4. If all the component and accessory connections have been made and the Controller has been powered ON, the Status Indicator light will be *green* **(see illustration at left).** If the Catheter, or footswitch, or return electrode connections described above have not been completed, the Controller will remain in the STANDBY mode and the Status Indicator light will remain *amber.*

Alair Controller Modes

SELF-TEST Mode – This mode lasts approximately 2 seconds and occurs automatically upon turning on the power to the Controller. The Controller performs a number of internal tests to verify correct functioning of the Controller, including:

- the function of all displays and the "RF On" tone
- the accuracy of the power, voltage, and current measurements
- the return pad current measurement accuracy
- the A/D calibration accuracy
- RAM functionality
- Firmware cyclical redundancy checks on the software

All of the indicators should light and the digital display should show [188]. A long tone should be heard during the SELF-TEST. This mode automatically transitions to either STANDBY or READY mode when it is completed.

STANDBY Mode – The STANDBY mode indicates that the Controller has passed its SELF-TEST and is standing by for component and accessory connections to be made in preparation for use. The Status Indicator light is *amber* when the Controller is in STANDBY mode. This mode is entered automatically after the SELF-TEST mode if any of the components or accessories (Catheter, footswitch, or patient return electrode) are not connected to the Controller.

READY Mode – The READY mode indicates that all required component and accessory connections (Catheter, footswitch, and patient return electrode) have been made and that the Controller is ready to deliver energy. The Status Indicator light is *green* when the Controller is in READY mode.

RF ON Mode – RF energy is being delivered in this mode. The RF Energy Icon light is *blue* when RF energy is being delivered. When the footswitch is depressed a short tone signals the start of RF energy delivery, and an intermittent dual tone sounds at 2-second intervals during RF energy delivery. The Controller delivers energy until the activation is complete or until the footswitch is depressed a second time, discontinuing RF energy delivery. After the completion of each activation, a long tone signals the termination of RF energy delivery and the Controller returns to the READY mode.

FAULT Mode – This mode indicates that a safety algorithm has been triggered or a non-recoverable error has occurred. In the case of a non-recoverable error, the digital display will flash [188] and all other indicators will flash. A non-recoverable error can only be reset by turning the Controller off, then on again. If FAULT mode persists, please contact BSC for repair or replacement information.

ALAIR CONTROLLER SHUT DOWN

Turn the power off using the ON/OFF switch that is located on the Power Entry Module on the rear panel of the Controller (See Figure 5).

MAINTENANCE AND TROUBLESHOOTING

Routine maintenance and calibration of the Controller are not required since the SELF-TEST Mode, activated automatically upon turning on the power to the Controller, verifies correct functioning of the Controller. The power cord assembly should be periodically checked for damage to the insulation or connectors.

In the event that the Controller requires repair or replacement, please contact BSC.

Only a qualified biomedical engineering representative at your institution should replace the Controller fuses.

If you encounter problems while using the Controller, check the following:

Problem/Error Message	Check the following
Controller does not power on	• Ensure that the switch at the rear of the Controller is in the "ON" position • Check power cord connection at the rear of the Controller • Check that the Controller power cord is connected to an appropriate power supply (see the Technical Specifications Section). • Have a qualified biomedical engineering representative at your institution check the Controller fuses or contact BSC for repair or replacement information.
The status indicator does not transition from the Standby Mode *(amber)* to the Ready Mode *(green)*	• Ensure that the Alair Catheter, patient return electrode and footswitch are all properly connected to the Controller
RF Energy is not delivered when the footswitch pedal is depressed	• Check that the Controller is powered on • Ensure that the Alair Catheter, the patient return electrode and footswitch are all properly connected to the Controller

Problem/Error Message	Check the following
Catheter icon on Controller is flashing *red* and the Controller is not responding	• Replace the Alair™ Catheter with a new Alair Catheter • The only exception to this instruction occurs if the Catheter array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling), the electrode array should be returned to room temperature and the catheter connector should be unplugged and re-connected to the Controller. If the Catheter Handle alarm persists, replace Catheter and continue with the bronchial thermoplasty procedure.
If any of these problems persist, please contact BSC for repair or replacement information.	

TECHNICAL SPECIFICATIONS

According to the IEC 60601-1 standard for medical devices, the Controller is classified as Class 1 equipment.

RF OUTPUT (not user adjustable)

Waveform - 461 kHz, sinusoidal

Maximum Output Values

- Power: 25 Watts; limited by software to 18 watts
- Voltage: 85 Vrms, 120 V peak, 240 V peak-to-peak
- Current: 0.90 Arms

Maximum Power Output over the Range of Load Resistance (see Figure 6): Actual power delivered will be automatically adjusted by the Controller based on temperature control algorithms.

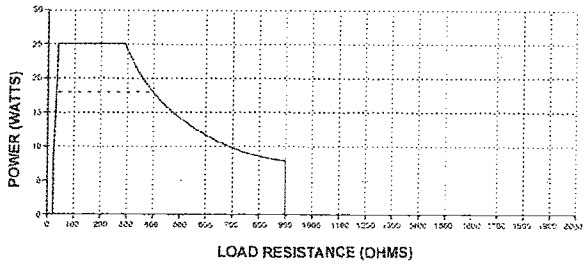


Figure 6: Maximum Power Given Load Resistance

Shutdown Limits

- Measured Temperature: < 10 °C or > 15 °C above set temperature
- Measured Impedance: < 25Ω, or > 900Ω

Mechanical Specifications

- Size: 5.3 in x 12.3 in x 15.4 in (13.5 cm x 31.2 cm x 39.1 cm)
- Measured Temperature Accuracy: ± 0.5% ± 2.5 °C
- Weight: 12.5 lbs. (5.6 kg)

Environmental Storage and Transport Conditions

- Storage temperature: 10 °C to 40 °C
- Transportation conditions: -40 °C to 70 °C
- Ensure that the unit is at room temperature for one hour before use if unit has been exposed to extreme temperature conditions

Operational Conditions

- Temperature: 18 °C to 40 °C
- Humidity: 30% to 75% (non-condensing)
- Pressure: ≥ 800 millibars

AC Input Specifications

- 100 – 120 V~ 50/60 Hz, 1.0 A
- 220 – 240 V~ 50 Hz, 0.5 A

Replace mains fuses as marked: 1.25 A/250 V, T-lag, 5x20 mm

EMC TEST LEVELS, COMPLIANCE LEVELS, AND ENVIRONMENTAL GUIDANCE

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The Alair RF Controller Model ATS 200 is intended for use in the electromagnetic environment specified below. The user of the Controller should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines NA - no input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (Continued)

The Alair™ RF Controller Model ATS 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Controller should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Controller requires continued operation during power interruptions, it is recommended that the Controller be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [1.17]\sqrt{P}$ MHz to 800 MHz $d = [1.17]\sqrt{P}$ MHz to 800 MHz $d = [2.33]\sqrt{P}$ MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Alair RF Controller Model ATS 200 or any of its components or accessories are used exceeds the applicable RF compliance level above, the Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or accessories or the entire Alair Bronchial Thermoplasty System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The Controller is intended for use in the electromagnetic environment specified below. The customer or the user of the Controller should assure that it is used in such an environment.		
Emissions Test	**Compliance Level**	**EMC Environmental Guidance**
RF Emissions CISPR 11	Group 1	The Controller must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The Controller is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

IEC Recommended Separation of RF Communication Equipment			
Recommended separation distances between portable and mobile RF communications equipment and the Alair™ RF Controller Model ATS 200 System			
The Alair RF Controller Model ATS 200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Controller as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter M**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{V_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 V_1 is 3 V_{rms} per the conducted emissions compliance level indicated in the table above

NOTE 4 E_1 is 3 V/m per the radiated emissions compliance level indicated in the table above

REFERENCES

1 Danek CJ, Lombard CM, Dungworth DL, Cox PG, Miller JD, Biggs MJ, Keast TM, Loomas BE, Wizeman WJ, Hogg JC, Leff AR. Reduction in airway hyperresponsiveness to methacholine by the application of RF energy in dogs. J Appl Physiol. 2004, 97(5):1946-53.

2 Brown RH, Wizeman W, Danek C, Mitzner W. Effect of bronchial thermoplasty on airway distensibility. Eur Respir J. 2005 Aug;26(2):277-82.

NO IMPLIED LICENSE

The purchase or rental of the Alair™ Controller does not grant a license, either expressly, by implication, estoppel or otherwise under any Boston Scientific patent right or patent covering or relating to any method or process in which the Alair Controller might be used. An implied license only exists for the Alair Controller used in conjunction with the Alair ATS 2-5 Catheter. Nothing herein shall be construed as a right or license to (a) make, use, sell, offer to sell, import, lease or distribute the Alair Controller with a non-Alair catheter or (b) sell or offer to sell the Alair Controller to customers that plan to make, have made, use, sell, offer to sell, import, lease or distribute the Alair Controller with a non-Alair catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants for one year from the date of purchase that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, cleaning and storage of the product as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Boston Scientific Corporation's control may directly affect the product and results obtained from it. Boston Scientific Corporation shall repair or replace, at its option, any part of the product that Boston Scientific Corporation determines was defective at time of shipment if notice thereof is received within one year of shipment. Boston Scientific Corporation shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the product.

Boston Scientific Corporation neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the product. BSC assumes no liability with respect to product use by a non-qualified physician; use contrary to documentation; use with a non-Alair catheter.

Buyer shall be responsible for the ongoing support and maintenance of the product not covered by this one-year warranty and after the one year warranty period has expired. Buyer may, at its sole cost and expense, purchase an extended warranty from Boston Scientific Corporation (BSC) to extend the term of this warranty.

Valleylab is a trademark of Covidien AG.

ConMed is a trademark of ConMed Corporation.

SYMBOL LEGEND

	Defibrillation-Proof Type CF Applied Part		Serial Number
	Neutral Electrode Isolated from Earth at High Frequencies		For Prescription use only
	Caution	SW1	Program Memory Enable, for Use Only by Qualified Service Personnel
	Alternating Current		[Blue Safety Sign] Follow Instructions For Use
	Equipotentiality Connector	REF	Catalog Number
	Fuses		Legal Manufacturer
	Power Off, Disconnected from the Mains	LOT	Lot Number
	Power On, Connected to the Mains	UPN	Product Number
	Catheter		Minimum Required Working Channel
	Patient Return Electrode		Recyclable Package
	Transmits and Accepts Radiofrequency Signals		Separate Collection

	Footswitch		Contents
	Serial Communication Port		Do not use if package is damaged
	Date of Manufacture		Consult Instructions For Use

Boston Scientific (Master Brand DFU Template 8in x 8in Global, 90106041AL), User Manual, MB, Alair Radiofrequency Controller, Canada/Mexico, 90795407-01B_pretrans

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

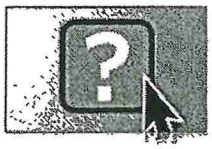
Recyclable Package

2013-02

90795407-01

Black (K) ΔE ≤5.0

BSC000692

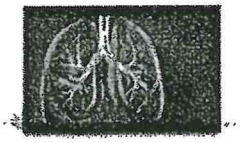


How much does asthma limit your choices?

Take this short quiz to find out.

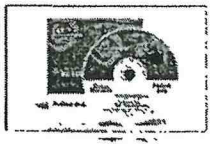
"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.



See how BT works

View an animation of the BT procedure in: English, Français, Deutsch, Italiano, or Español.



Start your BT journey today!

Request a FREE ASTHMA DVD and connect with the BT 1-2-3 Support Program.

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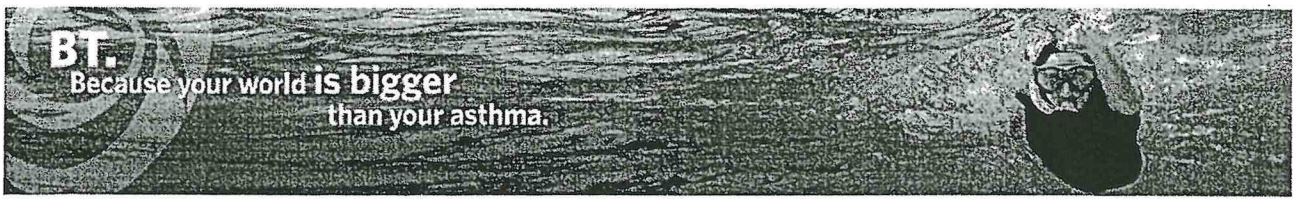
ENDO-142305-AE April 2014

EXHIBIT 6
WIT: Applicant
DATE: 4/9/15
MAUREEN O. POLLARD



Support for patients

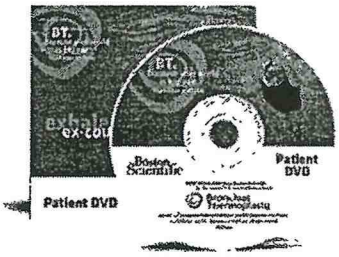
Physician information request

Home > Request more information > Support for patients

Start your BT journey with a FREE DVD and continued support

Ready for a bigger world with fewer asthma attacks?

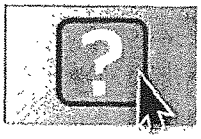
Complete the fields below to request your **FREE DVD** and connect with the BT 1-2-3 Support Program



Thank you for your interest in Bronchial Thermoplasty (BT). Your requested information is on its way to you. In the meantime, we invite you to explore the BTforAsthma.com website to learn more about this revolutionary procedure. If you have questions about BT, talk to your doctor or call our patient support line at 1-877-810-6060.

If you have any questions, please call our patient support line at 877-810-6060.

BSC Privacy Policy



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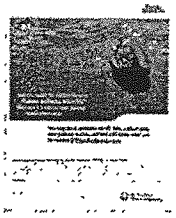
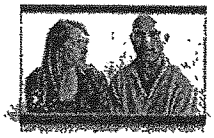


Download the BT Pamphlet for Patients.



"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.

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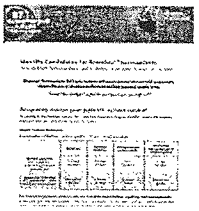
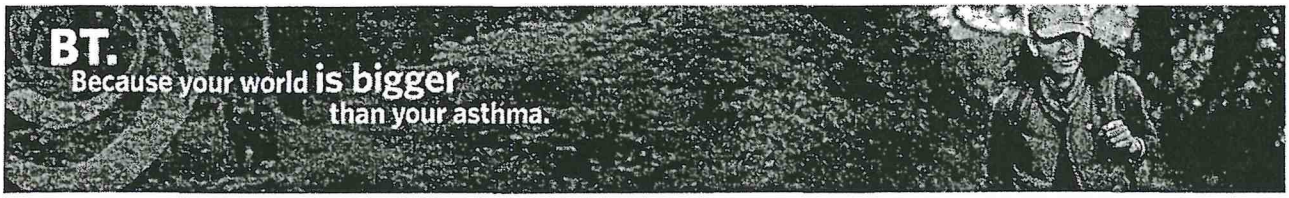


Help your patients recognize severe asthma by downloading the Asthma Impact Survey.

Support for physicians

Request more information about BT, BT training opportunities, and referring patients for treatment.

To assist patients in finding a BT Clinic, click here.



Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Home > Are you a BT candidate? > Current treatment options

Current treatment options for severe asthma

Many drugs can be prescribed to manage asthma symptoms. The severity of a patient's asthma often plays a large role in how successful a medication will be.

Some major types of currently-used asthma medications include:

Anti-inflammatory drugs. Inhaled corticosteroids are the key drugs used for controlling the underlying inflammation in asthma.

Bronchodilators widen the airways by relaxing airway smooth muscle, though they do not reverse airway inflammation. Bronchodilators come in 2 basic forms:

Maintenance medications, such as long-acting beta-agonists that work up to 12 hours.

Rescue (short-acting) medications that work quickly to ease severe asthma symptoms for 4 to 6 hours.

Medications for long-term control, including methylxanthines, anticholinergics, leukotriene inhibitors, and IgE inhibitors such as Xolair™.

Oral corticosteroids such as prednisone, when used for maintenance, are reserved for patients with severe asthma. These drugs typically serve as maintenance medications.

Medications have limitations

These medications treat asthma symptoms, but there are limitations—especially for patients with severe asthma. Studies show how hard it can be to manage asthma:

Limited efficacy in patients with severe asthma: A number of recent surveys show that symptoms are poorly controlled by asthma medications in patients with severe asthma. These patients often continue to experience frequent and serious symptoms despite taking regular doses of asthma medications.[1] Even this limited efficacy is only possible when the patient takes his or her medicine as prescribed, typically twice a day, every day.

Not taking medications as prescribed

A 2012 report by the Global Initiative for Asthma estimated that approximately 50% of patients with asthma do not take their medications as prescribed.[2] Non-compliance may be a reason for an increase in emergency room visits and hospitalizations among patients with severe asthma.

Side effects

Asthma medications can have potentially serious side effects. As with any medication, side effects become a greater concern when treatment is ongoing and as dosages increase, which is the case for patients with severe asthma.

Corticosteroids (oral steroids): Side effects of prednisone and other oral corticosteroids range from mild annoyances to serious, irreversible damage. These side effects occur more frequently with higher doses and longer treatment. Side effects with ongoing use include suppression of the immune system, adrenal system, and growth; osteoporosis; skin thinning; hypertension; cataracts; glaucoma; muscle weakness; and increased risk of infection. Short-term side effects include stomach upset, headache, dizziness, trouble sleeping, fluid retention, weight gain, high blood pressure, loss of potassium, elevation of cholesterol levels and vision changes.

Bronchodilators: The possible side effects of short-acting rescue medications include rapid heartbeat, skeletal muscle tremor, potassium deficiency, increased lactic acid, headache and hyperglycemia. Long-acting beta-agonists may even cause severe asthma symptoms in some patients, and death when those episodes occur.[2]

Other drugs: The side effects of omalizumab (Xolair™) include anaphylaxis, injection-site reactions, and viral infections.

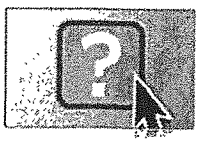
Lifestyle burdens

Because existing medications provide poor symptom control for some patients with severe asthma, they often must miss work or school. In addition, severe symptoms can require unscheduled doctor office visits, emergency room visits, and hospitalizations.

References:

1. Partridge MR. Examining the unmet need in adults with severe asthma *Eur Respir Rev.* 2007;16:104,67-72.

2. GINA (Global Initiative for Asthma) 2012 Global Strategy for Asthma Management and Prevention Workshop report in collaboration with National Institutes of Health (NIH) National Heart, Lung, and Blood Institute NHLB/WHO 2007.



How much does asthma limit your choices?

Take this short quiz to find out.

Learn more about BT with this FREE DVD for patients with asthma.

"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.

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Proven benefits

About Bronchial Thermoplasty

Asthma and your airways

How BT is performed

Home > Bronchial Thermoplasty > About Bronchial Thermoplasty

You deserve a fuller life—now a revolutionary procedure can help!

If you are taking asthma medications—but still have asthma attacks—Bronchial Thermoplasty (BT) may be right for you.

In a clinical study, 79% of severe asthma patients treated with BT reported significant improvements in their asthma-related quality of life, compared with patients who did not receive BT treatment.[1]

What makes BT different from asthma medications?

Short-term (rescue) asthma medications offer temporary relief by relaxing the airway muscle so that it does not block the airways during an asthma attack.

BT is not a medication, and works in a very different way to provide long-lasting relief.

BT, delivered by the Alair™ System, is a safe outpatient procedure that uses mild heat to actually reduce the amount of excess airway smooth muscle tissue in the airways. Learn more about how BT is performed. Less muscle tissue means less airway constriction during an asthma attack. Patients can breathe more easily—and are less likely to have an asthma attack.[1]

Fewer asthma attacks means less need for the associated oral steroid treatment—and its side effects.

BT does not replace your asthma medication. Instead, BT works with your asthma medications to give you added, long-lasting protection from serious asthma symptoms.

In a clinical trial, BT was also proven to reduce asthma attacks, emergency rooms visits for respiratory symptoms, and time lost from work, school, and other activities due to asthma symptoms.[1]

Hear what other patients have experienced since their BT procedure.

Reference.
1. Castro M, et al, for the AIR2 Trial Study Group. *Am J Respir Crit Care Med.* 2010;181:116-124.

How much does asthma limit your choices?
Take this short quiz to find out.

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Download the BT Pamphlet for Patients.

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Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Are you a BT candidate?

You may be eligible for Bronchial Thermoplasty (BT) treatment if:

You are 18 years or older with severe asthma, AND

You have asthma symptoms despite taking inhaled corticosteroids and long-acting beta-agonists such as Advair™, Dulera™, or Symbicort™.

Take the Asthma Impact Survey to discover more about how asthma symptoms may be affecting your life.

You are not a candidate for BT if:

You have a pacemaker, internal defibrillator, or other implantable electronic device.

You have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines.

You've been treated previously with BT.

Who performs the BT procedure?

BT is performed by a specially trained pulmonologist. If your regular doctor currently managing your asthma is an allergist, family practice physician, general practitioner, internist or other physician, he or she will be able to refer you to a BT Clinic for a consultation with a pulmonologist. After your BT treatment is completed, you will return to your regular asthma doctor to manage your asthma.

For help with discussing this treatment with your doctor:

Complete the **Asthma Impact Survey.**

Share your survey results with the physician who manages your asthma.

Learn more about BT with this FREE DVD for patients with asthma.

"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.

Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Connect to the
BT 1 2 3
SUPPORT PROGRAM

Ready for a life less defined by asthma? Get the support and information you need!

START HERE

EXHIBIT 11
WIT: Applicant
DATE: 10/9/13
MAUREEN O. POLLARD

Home > Are you a BT candidate? > Take the Asthma Impact Survey

How much does asthma affect your quality of life?

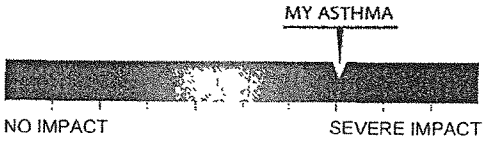
See for yourself: If asthma is limiting the choices you make in life, perhaps it's time to look beyond medication alone. The following survey was created by a doctor and can help you recognize the many ways severe asthma may be affecting your life.

Be sure to share your answers with your doctor—and discover how Bronchial Thermoplasty (BT) may help you live a fuller life. BT, delivered by the Alair™ System, is not another medication—it's a revolutionary and safe procedure proven to provide a long-lasting reduction in asthma attacks.[1]

THE ASTHMA IMPACT SURVEY™

Congratulations on taking an important step toward a new life with fewer asthma attacks

Your responses indicate that asthma has a
severe impact
on your quality of life

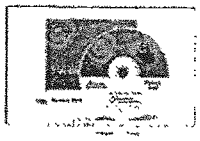


Print my Survey results and letter to my doctor here.

This survey is a diagnostic tool to assess the impact asthma has on your daily lifestyle. You should check with your doctor to make sure that you are taking your medication appropriately and consistently. Your medication dosage may need to be adjusted to help provide better symptom control. If you are taking the maximum tolerated medication regularly and continue to have asthma symptoms that impact your daily life, you may be a candidate for the BT treatment and you should consult an asthma specialist to learn more about your options.

Take this survey and the letter with you to your doctor. It will help your doctor determine whether you might be a candidate for BT.

References
1. Wechsler M, et al, for the AIR2 Trial Study Group. *J Allergy Clin Immunol.* 2013;132.1295-1302.



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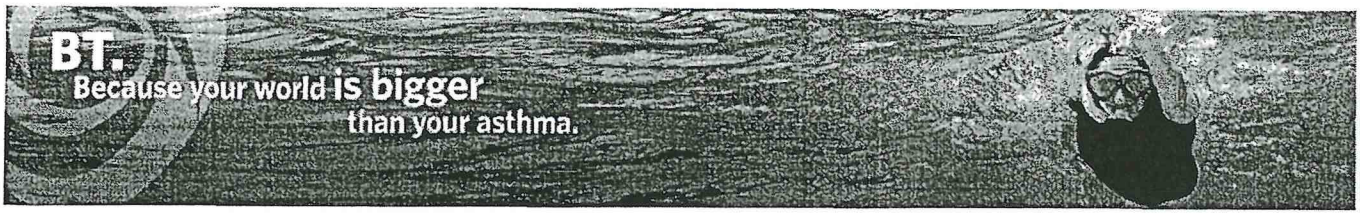
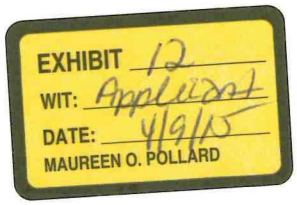


US availability

International Availability



Find a BT Clinic

Type in your zip code or click on a state on the US map to see a list of physicians offering Bronchial Thermoplasty (BT) in that state.

Boston Scientific maintains an updated list of physicians who are trained to perform BT. The list is based upon location only.

If there isn't a BT Clinic in your area, contact Boston Scientific.

Not in the United States? View a list of hospitals outside of the US with BT Clinics

(* Required)

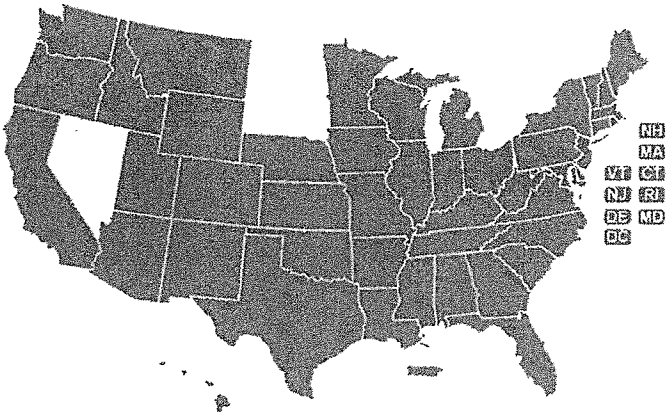
Zip Code: *

How far are you willing to travel? * 50 miles

Search

OR

Find Physicians in your state: Select



ENDO-142305-AE April 2014

Patient stories

Physician stories

In the news

Press releases

Home > Real people, real results > Patient stories

Real people, real results

Listen and watch as people with severe asthma discuss the dramatic difference Bronchial Thermoplasty (BT) has made in their lives.

Please note that individual BT treatment results may vary. BT is an add-on therapy that supplements your current asthma medications. BT, delivered by the Alair™ System, is

indicated for the treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

VIEW VIDEO

Angel's Story

"I've been able to cut the grass. I've been able to work on my car. I wasn't able to travel. I've been able to travel, something I haven't done for years."

VIEW VIDEO

Laretta's Story

"Now I can live life and go and do those fun activities that I hadn't done before. If you really want to live life and you really don't want a disease that's controlling your life or defining you, have BT."

VIEW VIDEO

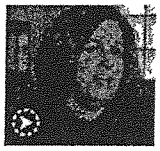
Mike's and Jenny's Story

"I just feel like I'm free... I feel like the sky's the limit."

VIEW VIDEO

Chris's Story

"It was a moment of revelation. It's that sun breaking through the clouds and you go, 'It worked.'"



VIEW VIDEO

Debbie's Story

"I noticed doing things around the house, things that I would get out of breath with before. Like carrying up laundry from the basement, just something as simple as that... I wasn't as winded."

VIEW VIDEO

John's Story

"I've gone from torture to being able to live my life, I feel like I've got a second chance."

VIEW VIDEO

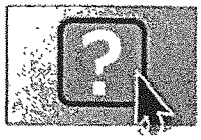
Brenda's Story

"I would highly recommend this to somebody else. It's just a simple procedure and it's a great benefit."

Jeff's Story

"My life has changed due to the treatment in a way that I'm not afraid to go hiking in the mountains."

VIEW VIDEO



How much does asthma limit your choices?

Take this short quiz to find out.

Learn more about BT with this FREE DVD for patients with asthma.

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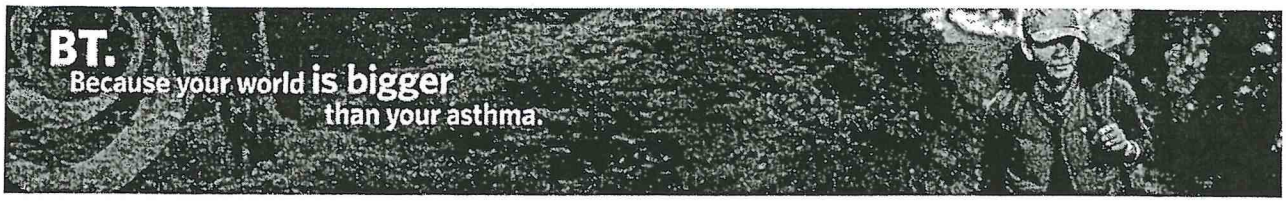
ENDO-142305-AE April 2014



Patient stories

Physician stories

In the news

Press releases

Home > Real people, real results > Physician stories

Physician stories

Listen and watch as physicians discuss the positive results they've seen in their patients with this revolutionary treatment for severe asthma.

Please note that individual BT treatment results may vary. BT is an add-on therapy to current asthma medications. BT, delivered by the Alair™ System, is indicated for the

treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

VIEW VIDEO

Dr. Mario Castro

Washington University, St. Louis, MO
"The benefits that we have seen with Bronchial Thermoplasty include an improvement in their quality of life, an improvement in their asthma symptoms, a decrease in the frequency that they end up in the emergency room and in turn towards decreased hospitalizations as well, and we also see that they are missing less work or school after the treatment itself."

VIEW VIDEO

Dr. Gerard P. Cox

McMaster University, St. Joseph's Healthcare, Hamilton, Ontario, Canada
"Bronchial Thermoplasty represents an opportunity, different from anything that's been done before therapeutically for these patients to help control asthma."

VIEW VIDEO

Dr. David R. Duhamel

Virginia Hospital Center, Arlington, VA
"I'm very excited about this new technology. I really think it offers a new opportunity to greatly impact our patient's lives."

VIEW VIDEO

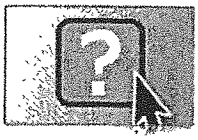
Dr. Jeff B. Hales

Virginia Hospital Center, Arlington, VA
"The patients that I followed as an assessment physician through this AIR2 trial are walking on cloud nine."

VIEW VIDEO

Dr. Armin Ernst and Patricia DiGiusto

"Patricia was the perfect first patient for any new procedure that you want to introduce into a hospital. She was looking for other options and really came to us to get a better idea of what Bronchial Thermoplasty was all about."



How much does asthma limit your choices?
Take this short quiz to find out.

Learn more about BT with this FREE DVD for patients with asthma.

Do your asthma patients know what they are missing?

Now, a revolutionary procedure can help them lead a fuller life.

Frequent asthma exacerbations can have a profound impact on a patient's lifestyle. Severe asthma places limitations on work, school, and other activities. However, patients may not acknowledge—or even recognize—that their asthma symptoms are severe. Over time, these patients may try to avoid exacerbations by modifying daily activities—even those that they enjoy.

Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe, minimally invasive outpatient procedure for the treatment of severe asthma in adults. If you have patients who you believe may benefit from this procedure, the information in this section will help you identify the appropriate BT candidates.

Who is appropriate for BT?

- Adult patients with severe asthma (at least 18 years old)
- Patients whose asthma is not well controlled despite taking a combination of inhaled corticosteroids and long-acting beta-agonists such as Advair™, Symbicort™, or Dulera™
- Patients able to safely undergo bronchoscopy per hospital guidelines

Help your patients recognize severe asthma: The online **Asthma Impact Survey** is intended to help you determine how asthma may be influencing the choices your patient makes every day.

A recent study has shown that the interference of asthma with daily activities is a key predictor for the risk of future exacerbations.[1] In fact, in an analysis of the quality-of-life survey you see here, patients with severe health impairment related to asthma were 70% to 4 times as likely to manifest adverse outcomes like ER visits and oral corticosteroid use.[2]

Who is *not* appropriate for BT?

- Patients who have a pacemaker, internal defibrillator, or other implantable electronic device
- Patients who have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines
- Patients who have previously been treated with BT

BT should be delayed when any of the following conditions are present:

- Active respiratory infection
- Asthma exacerbation or changing dose of systemic corticosteroids (up or down) in the past 14 days
- Known coagulopathy

Patient is unable to stop taking anticoagulants, antiplatelet agents, aspirin, or non-steroidal anti-inflammatory medications (NSAIDS) before the procedure with physician guidance

Who performs the BT procedure?

Pulmonologists who are experienced in bronchoscopy

BT training is required, and includes:

- Review of Alair System Catheter Directions for Use and Controller Operator's Manual
- Guided didactic instruction in computer simulation-based Bronchial Thermoplasty Learning Center
- Detailed in-service training of the Alair System
- Hands-on training with Alair System in a lung model prior to initial cases
- Proctoring of initial cases by Boston Scientific Health Care Industry Representative (HCIR)
- Ongoing support of cases when requested

Where is the procedure performed?

At facilities that are appropriately equipped to perform bronchoscopy and are equipped to handle respiratory emergencies

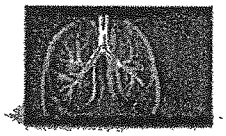
How is the procedure performed?

Click here to view the video

Review a complete list of **indications for use, contraindications and precautions**.

If you would like to refer a patient for BT or are interested in performing the procedure yourself, please complete the **Physician information request form**.

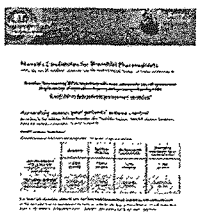
References.
1. Schatz M, et al *Chest* 2012;41:66-72
2. Schatz M, et al *J Allergy Clin Immunol.* 2011;128;1:44-49.e1.



See how BT works

View an animation of the BT procedure in: English, Français, Deutsch, Italiano, or Español

Find out why physicians are excited about bringing BT to patients with severe asthma.



Help your patients recognize severe asthma by

downloading the Asthma Impact Survey.

Support for physicians

Request more information about BT, BT training opportunities, and referring patients for treatment.

To assist patients in finding a BT Clinic, click here.

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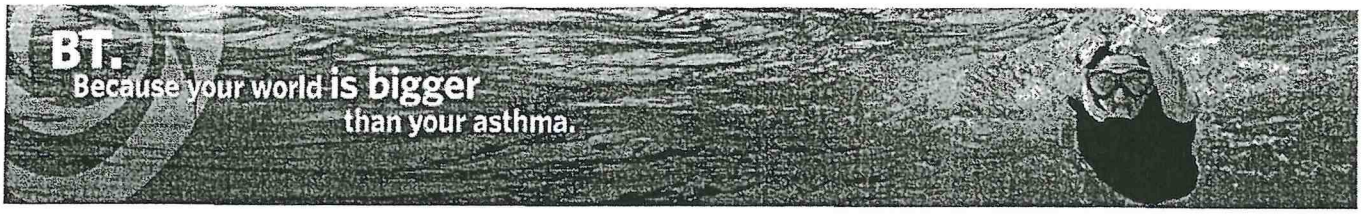

Support for patients

Physician information request

Home > Request more information > Physician information request

Physician information request

If you would like more information on Bronchial Thermoplasty (BT), please complete the information requested below and a representative from Boston Scientific will follow up with you.

Please select one of the following:
O I am interested in referring patients for Bronchial Thermoplasty treatment.
O I currently provide or am interested in providing Bronchial Thermoplasty treatments to patients.

(* Required)

Title	Please Select...
Specialty	Please Select...
First Name *	
Last Name *	
Hospital/Clinic *	
Address 1 *	
Address 2	
City *	
State *	Please Select...
Zip/Postal code*	
Country	
Phone	
Email *	
I currently perform bronchoscopy	O Yes O No
I perform approximately the following number of bronchoscopies per month	Please Select...
I see in my office the following number of severe asthma patients per month	Please Select...
How did you hear about us? *	Please Select...

☐ I am interested in learning more about the BT training program

☐ I am interested in referring a patient(s) for BT

☐ I would like to receive more information on BT

Comments:

Submit

Boston Scientific Corporation
150 Baytech Drive
San Jose, CA 95134
T: 877-810-6060 F: 408-419-0199

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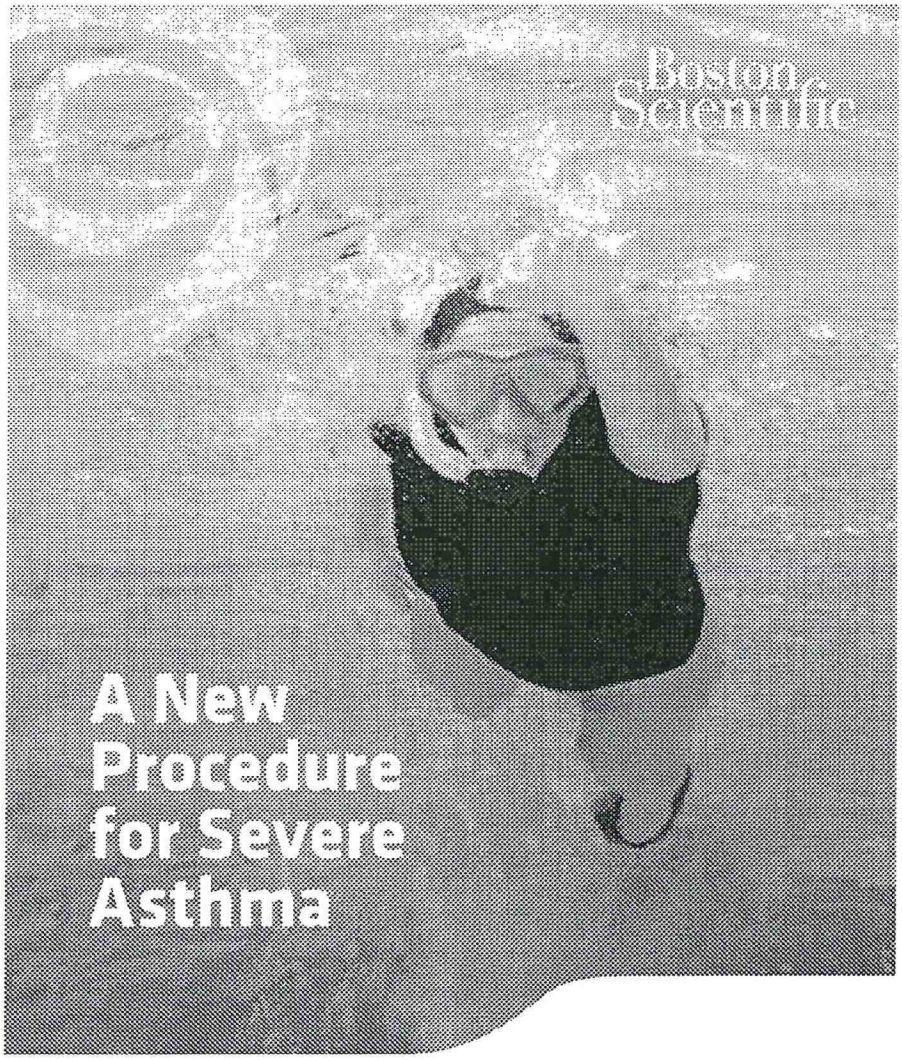


This brochure describes a new procedure for treating severe asthma in adults.

NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

Contents

About severe asthma

What happens when you have severe asthma?

Air travels in and out of your lungs through airways, which are tubes. There are tiny muscles in the walls of the airways. People who have severe asthma have larger muscles in their airways than other people. The airways close down when these muscles contract.

What happens when your airways close down?

When airways close down it can be harder to breathe. Your chest may feel tight. You may wheeze or cough. Asthma medicines usually open up the airways. These medicines do not always work well in patients who have severe asthma.

Why do doctors do this treatment?

You have severe asthma. Your asthma is severe because the asthma drugs you take now do not control your asthma symptoms.

Your doctor wants to use the Alair™ System to treat your severe asthma. This treatment is called Bronchial Thermoplasty (BT). BT is a procedure and not an asthma medicine. Your doctor thinks your health is good enough to have this treatment.

If you decide to have this treatment, you will need to do what your doctor asks you to do or you may be harmed.

What is the Alair System?

The Alair System is the tool that your doctor will use to perform BT. The Alair System has two main parts:

- A small tube with 4 wires at the end. See **Figure 1**.
- A machine that heats the wires

You need to decide if BT is right for you. You will be treated by a doctor who has been trained and knows how to use it correctly.

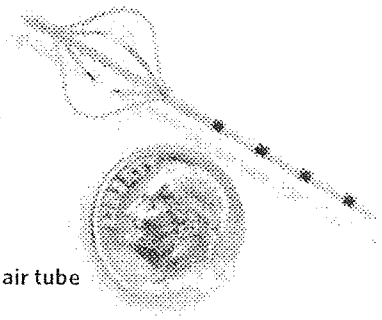


Figure 1: Actual size of tip of Alair tube

What is Bronchial Thermoplasty?

The Alair™ System mildly heats your airway walls. This heating reduces some of the extra muscle present in the airways. This may allow your airways to stay more open and help you breathe better.

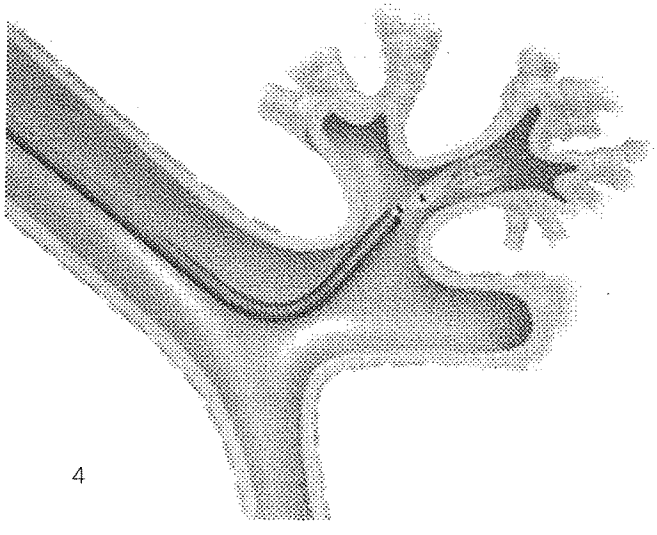
Who can have this treatment?
(Indication for Use)

The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

Who cannot have this treatment?
(Contraindications)

You cannot have this treatment if you have:

- **An implant with electronics.** Tell your doctor if you have any implants with electronics, such as a pacemaker. BT may keep the implant from working correctly.
- **Problems taking certain medicines.** Tell your doctor if you have ever had a problem taking any kind of medicine. Your doctor will use some medicines to perform BT. Your doctor needs to make sure the medicine he or she uses will not hurt you.
- **Have had this treatment before.** Tell your doctor if you have had BT before.
- **You cannot have this treatment if you are less than 18 years old.** No one has tested BT in patients younger than 18 years.

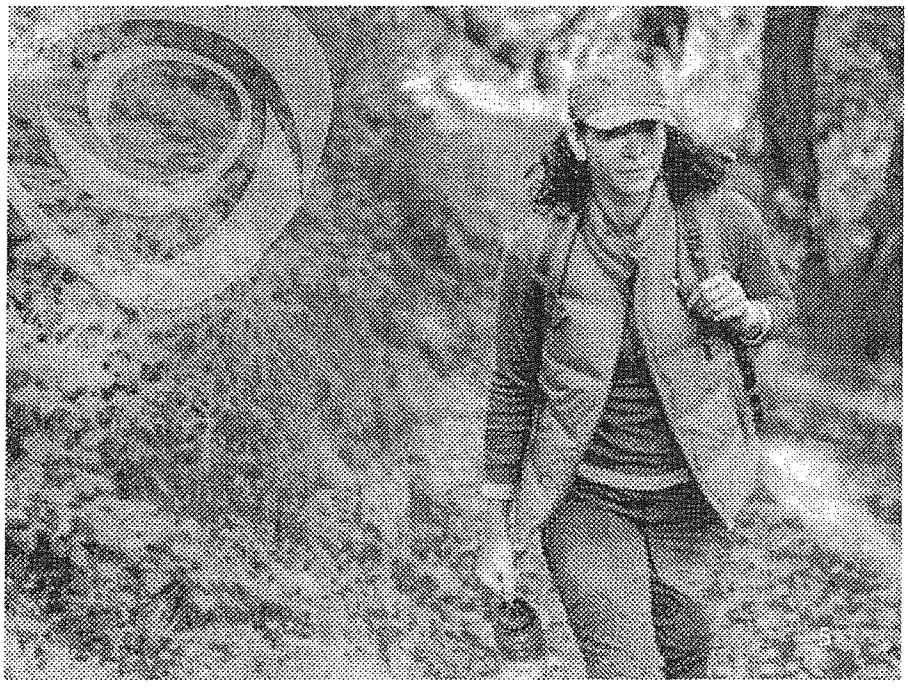


You cannot have this treatment while the following conditions are present:

- **An active respiratory infection.** Tell your doctor if you think you have an infection, fever, or your asthma is worse than usual. If your infection is in your lungs or airway, BT may harm you.
- **Have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks.** Tell your doctor if either of these has happened in the last 2 weeks. If you have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks, BT may harm you.
- **A blood-clotting problem.** Tell your doctor if you take any drugs to keep your blood from clotting. Some call these drugs blood thinners. If you have a blood-clotting problem, BT may harm you.

Clinical study

In 2007, doctors studied nearly 300 patients who had severe asthma. In this study, they saw how well BT worked and what side effects patients had. Doctors treated about 200 people with BT. This was the "BT Group." Doctors treated another group in a similar way, but they did not heat their airways. This was the "Sham Group." Patients did not know which group they were in. Doctors studied these patients for a year after their last treatment. We do not know how well patients did beyond one year. This is still being studied.



What are the risks and side effects of BT?

Right after their doctors treated them, many patients in the study had side effects. **Table 1** shows how many people had each side effect. The table shows side effects that occurred in 3 or more in every 100 patients in the BT group.

How to read this table:

- Short-term: from start of first treatment until 6 weeks after third treatment.
- Long-term: from 6 weeks after last treatment until 1 year after last treatment.
- In the table, some patients had more than one side effect.
- Look at **Table 1**.
  - Think of a group of 100 patients.
  - Look at the column that says "Short-term period."
  - Go down that column to the row that reads "More than one symptom of asthma."
  - This row means that 52 out of every 100 patients in the BT Group had "more than one symptom of asthma" sometime after their first treatment until 6 weeks after their third treatment.
  - On the same row, now look at the "Long-term period" column.
  - You see there were 27 out of every 100 patients in the BT Group who had "more than one symptom of asthma" in the long-term period.
  - The 52 and the 27 are not separate groups of patients. Some patients may be counted in both groups:
    - One or more patients who had a "short-term period" effect may have also had a "long-term period" effect. Meaning he or she did not get better.
    - One or more patients who did not have a "short-term period" effect may have had a "long-term period" effect. Meaning he or she got worse later.
    - One or more patients who had a "short-term period" effect may not have had a "long-term period" effect. Meaning their problem went away.

Other side effects related to the lungs, ear, nose, and throat occurred in the short-term or long-term periods in the BT group. The following side effects occurred in 1 or more in every 100 patients in the BT group, but less often than the side effects in **Table 1**: abnormal breath sounds, acute swelling of the airways, blocked airways, bleeding during the procedure, bloody mucus, bloody nose, chest

Table 1: Short-term and Long-term side effects

Type of Side Effect	Short-term period		Long-term period	
	BT Group	Sham Group	BT Group	Sham Group
Related to Breathing	OUT OF EVERY 100 PATIENTS			
More than one symptom of asthma	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Shortness of breath	11	6	2	1
Chest discomfort	9	10	2	1
Infection in the lower airways	8	2	3	6
Productive cough	7	9	3	4
Collapse of part of the lung	5	0	0	0
Swelling of the airways	4	2	7	5
Bleeding	3	0	0	0
Related to Ear, Nose, and Throat				
Infection in the upper airways	20	11	30	26
Swelling of the nose and/or throat	5	7	11	5
Throat irritation	5	12	1	3
Infection in the upper airways caused by a virus	4	2	6	7
Sinusitis	3	5	6	7
Acute sinusitis	3	2	4	8
Sore throat	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
All Other				
Headaches	14	9	5	3
Back pain	5	6	3	5
Fever	4	2	0	1
Influenza	4	2	4	12
Upset stomach	4	2	2	4
Anxiety	4	0	1	2
Nausea	3	4	1	1
High blood pressure	3	2	3	3
Urinary tract infection	1	1	3	1

*One instance of bleeding occurred 31 days after a BT treatment and was treated with a medical procedure.

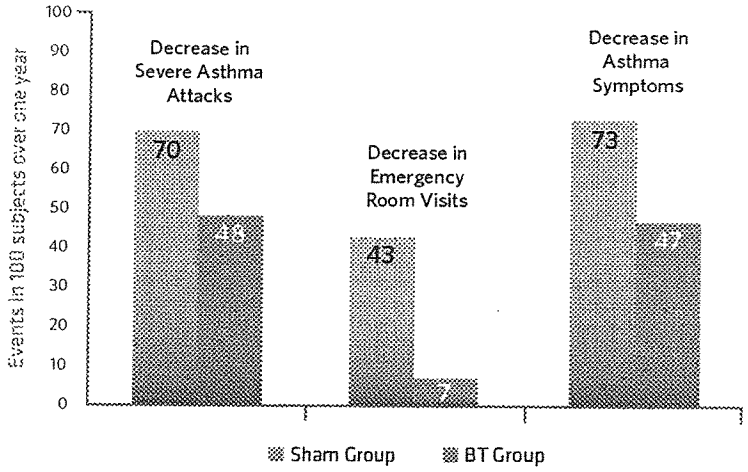
congestion, increased mucus in upper airways, infection in the lower airways caused by a virus, low oxygen in the blood, narrowing of airways, nasal congestion, pneumonia, runny nose, and swelling of the throat caused by a virus.

Ask your doctor about other uncommon side effects that are not related to the lungs, ear, nose, and throat.

What are the benefits of BT?

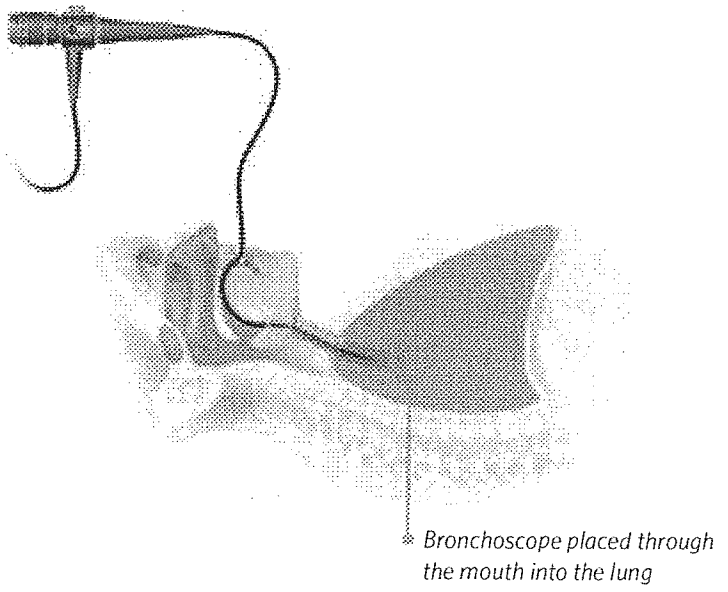
The study showed that the people in the BT Group had fewer severe asthma attacks, visits to the emergency room, and asthma symptoms, as shown in **Figure 2**.

Figure 2. Benefits of BT



The BT Group also lost on average 3 fewer days per patient from work, school, or other daily activities due to asthma symptoms. This was for one year after treatment compared to the Sham Group. This is not shown in **Figure 2**.

Figure 3. Placement of bronchoscope into your lungs

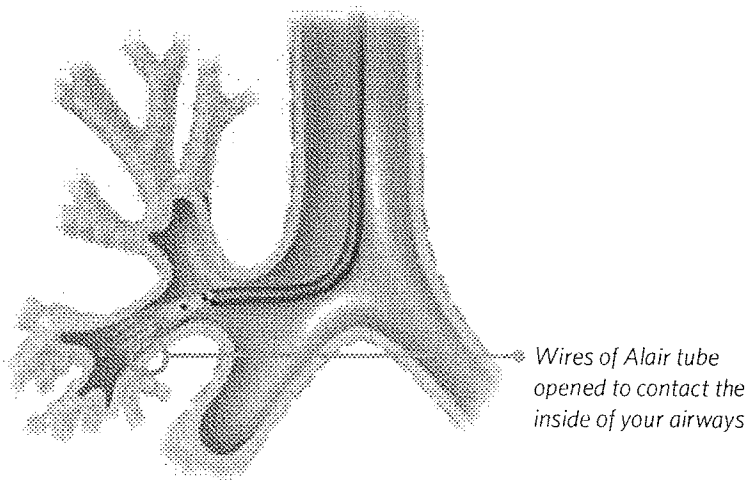


What will happen if you decide to have the BT treatment for your severe asthma?

- There will be 3 treatments. There will be 3 weeks in between each treatment.
- You will prepare for each treatment by taking a 50 mg steroid pill by mouth once a day for 3 days before the treatment.
- You will also take a 50 mg steroid pill on the day of the treatment.
- On each BT treatment day, your doctor will test your lungs. He or she will do this by checking how much air you can blow out.
- Your doctor will make sure you don't have an infection. An infection would delay the treatment.
- Your doctor will tell you what he or she will do during BT.
- Your doctor will:

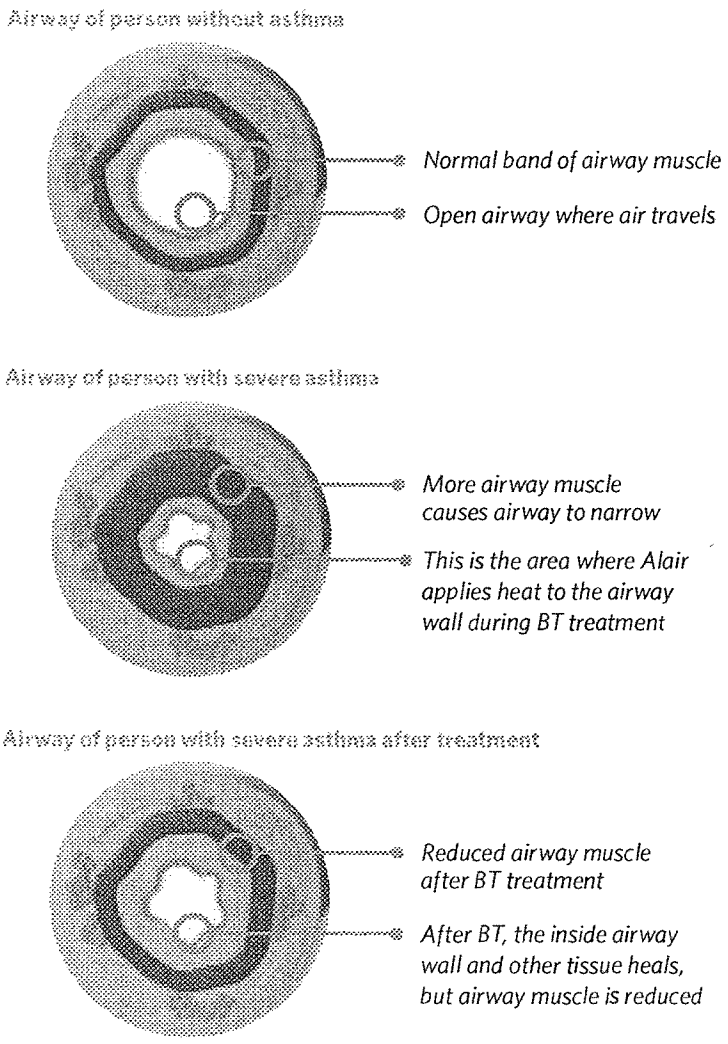
  1. Give you medicine to make you sleepy.
  2. Put a small tube called a bronchoscope through your mouth into your airways. See **Figure 3**.
  3. Put the smaller Alair™ tube through the bronchoscope. The wires on its end will touch your airways. See **Figure 4**.

Figure 4. Placement of Alair tube in your lungs



4. Heat the wires on the end of the small Alair™ tube to reduce some of the airway muscle tissue. You won't feel this because your doctor gave you medicine. See **Figure 5** for how airways look before and after Bronchial Thermoplasty treatment.

Figure 5. Airways before and after BT treatment



5. Move the small Alair tube to more places and treat them the same way.
6. Take the small Alair tube and the bronchoscope out.
7. Watch over you as you wake up and recover.

What happens after each BT treatment?

- You need to take a 50 mg steroid pill the day after.
- Your doctor will contact you by phone to check on you:
  - The day after your treatment
  - The day after that, and
  - A week after your treatment
- You will still need to take your asthma medicine.

After your airways heal from your first treatment, you will go back to your doctor for your second treatment. Your doctor will treat more of your airways. After you get well from that, your doctor will treat the rest of your airways in your third treatment.

Use your rescue inhaler if your asthma symptoms get bad. Tell your doctor if you needed to use your rescue inhaler.

When to call the doctor?

If you have this treatment, contact your doctor if your asthma symptoms get worse and do not get better after using your rescue inhaler.

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events:

The Alair™ Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. The Alair System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms.

Boston Scientific

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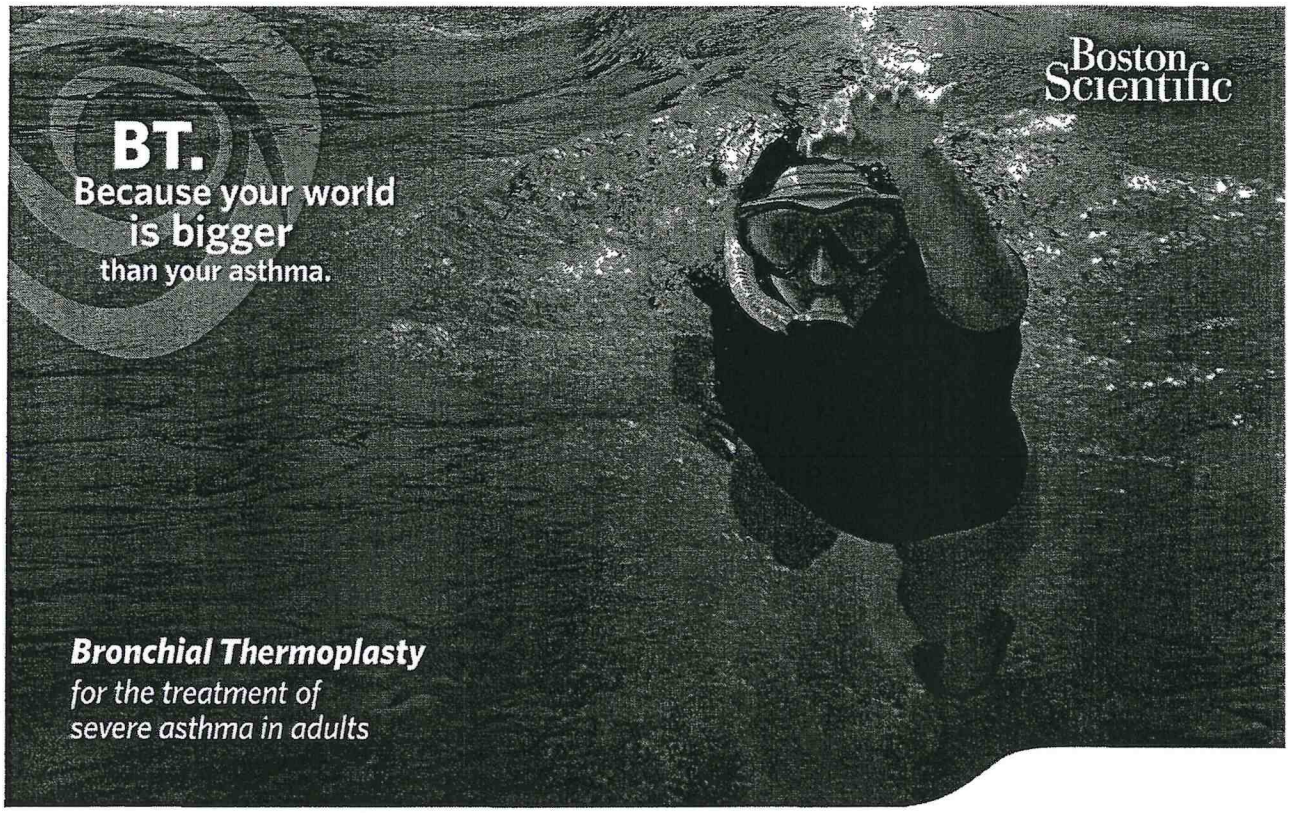
www.BTforAsthma.com



Are you ready for a fuller life with

fewer asthma attacks?

Perhaps it's time to look
beyond medication alone.

Bronchial Thermoplasty™

EXHIBIT 3
WIT: Opposer
DATE: 4/9/15
MAUREEN O. POLLARD

It's not a medication— it's revolutionary relief for severe asthma

Are you

- **taking multiple asthma medications but still having asthma attacks?**
- **adjusting your lifestyle to avoid asthma triggers?**
- **missing work, school, or daily activities because of asthma?**

If the answer is yes, you might be a candidate for Bronchial Thermoplasty (BT) delivered by the Alair™ System. It's a safe outpatient procedure that provides a long-lasting reduction in asthma attacks for people with severe asthma.[1] **Fewer asthma attacks means less need for the associated oral steroid treatment and its side effects.**

BT is clinically proven to work. In a clinical study, patients with severe asthma who were treated with BT experienced:

32% **decrease** in severe asthma **attacks**[2]

84% **reduction** in asthma-related **emergency room visits**[2]

66% **fewer days lost** from **work, school,** and daily activities due to asthma[2]

Additionally:

79% of patients who were treated with BT reported a **significant improvement** in their asthma-related **quality of life**[2]

Reductions in asthma attacks, emergency room visits, and hospitalizations were shown to extend through a 2-year follow-up period.[1]

BT, delivered by the Alair System, is a safe outpatient procedure

- As with any procedure, there are risks, and individual results may vary.
- The most common side effect of BT is a temporary worsening of respiratory-related symptoms. These events typically occur within one day of the BT procedure and usually resolve within a week with proper care.
- There is a small risk (3.4% per procedure) that symptoms may require hospitalization.

BT is indicated for the treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

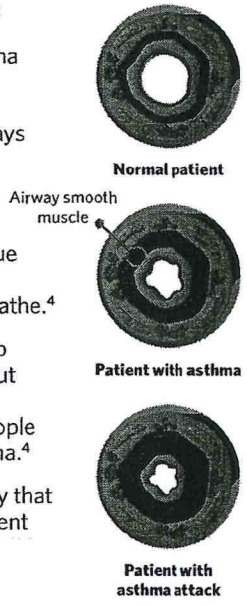
How BT is performed

- During the procedure a tiny, carefully controlled device delivers mild heat to the smooth muscle of the airways in your lungs.
- No incision is needed, because the procedure is performed with a bronchoscope inserted through the nose or mouth.
- When your BT treatment is complete, you will return to your regular asthma-treating doctor to continue managing your asthma.

BT reduces asthma attacks by reducing airway smooth-muscle tissue

- People who have asthma have more airway smooth-muscle tissue surrounding their airways than people who don't have asthma.[3-5]
- During an asthma attack, this excess tissue constricts the airways, making it harder to breathe.[4]
- Asthma medicines help open up the airways, but these medicines don't always work well in people who have severe asthma.[4]
- BT is an add-on therapy that supplements your current asthma medications.

Airway cross sections



Treatment with BT actually reduces the amount of excess smooth-muscle tissue in the airways. With less of this tissue, the airways constrict less, reducing asthma attacks and making breathing easier.[2]

NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

Is asthma limiting your life?

You may be a candidate for Bronchial Thermoplasty (BT).

Take a short quiz, hear patient stories, and find a BT Clinic near you by visiting BTforAsthma.com.

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events: The Alair™ Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. The Alair System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be treated with the Alair System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms. Rx only.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions, and warnings can be found with product labeling.

References: 1. Castro M, et al *Ann Allergy Asthma Immunol.* 2011,107 65-70 **2.** Castro M, et al, for the AIR2 Trial Study Group. *Am J Respir Crit Care Med.* 2010,181 116-124. **3.** Woodruff PG, et al. *Am J Respir Crit Care Med.* 2004,169 1001-1006. **4.** Cox PG, et al. *Eur Respir J.* 2004;24 659-663 **5.** Wechsler ME. *Allergy Asthma Proc.* 2008,29.1-6.

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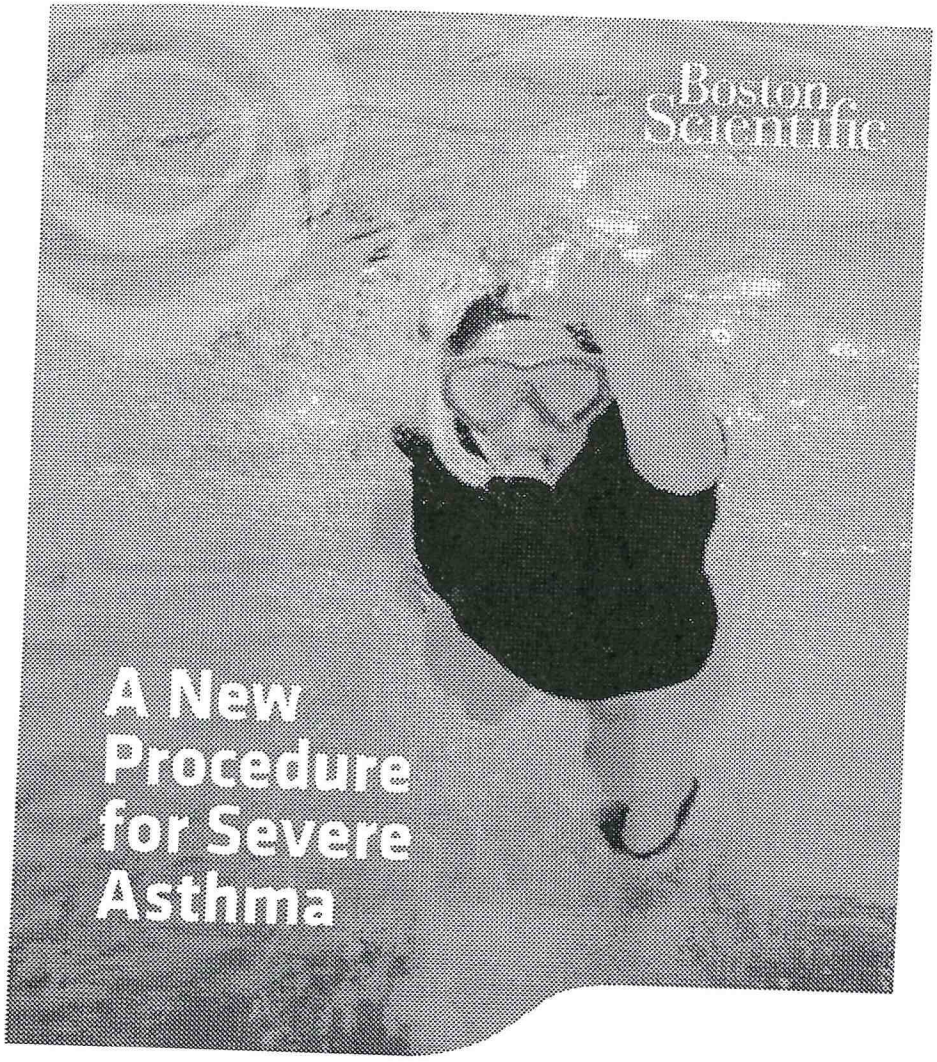


This brochure describes a new procedure for treating severe asthma in adults.

EXHIBIT 4
WIT: Dapoor
DATE: 4/9/15
MAUREEN O. POLLARD

NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

What is Bronchial Thermoplasty?

The Alair™ System mildly heats your airway walls. This heating reduces some of the extra muscle present in the airways. This may allow your airways to stay more open and help you breathe better.

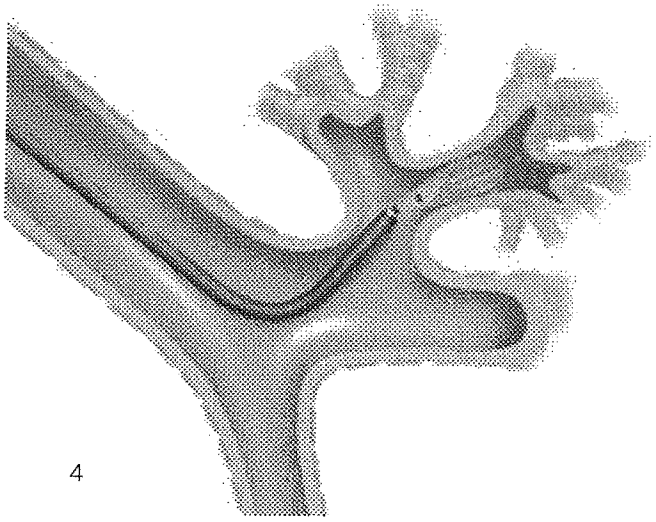
Who can have this treatment?
(Indication for Use)

The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

Who cannot have this treatment?
(Contraindications)

You cannot have this treatment if you have:

- **An implant with electronics.** Tell your doctor if you have any implants with electronics, such as a pacemaker. BT may keep the implant from working correctly.
- **Problems taking certain medicines.** Tell your doctor if you have ever had a problem taking any kind of medicine. Your doctor will use some medicines to perform BT. Your doctor needs to make sure the medicine he or she uses will not hurt you.
- **Have had this treatment before.** Tell your doctor if you have had BT before.
- **You cannot have this treatment if you are less than 18 years old.** No one has tested BT in patients younger than 18 years.

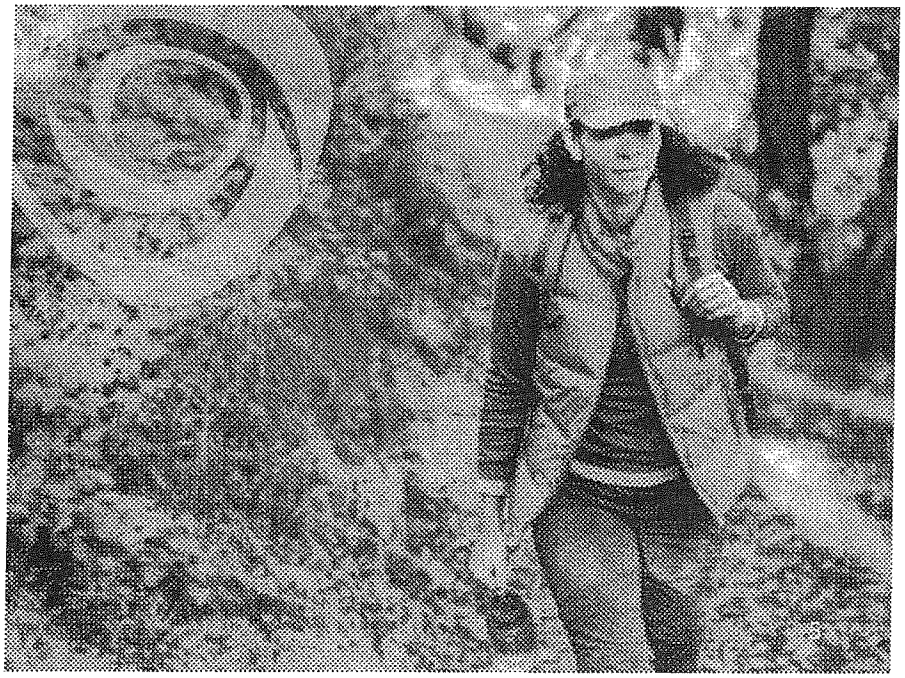


You cannot have this treatment while the following conditions are present:

- **An active respiratory infection.** Tell your doctor if you think you have an infection, fever, or your asthma is worse than usual. If your infection is in your lungs or airway, BT may harm you.
- **Have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks.** Tell your doctor if either of these has happened in the last 2 weeks. If you have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks, BT may harm you.
- **A blood-clotting problem.** Tell your doctor if you take any drugs to keep your blood from clotting. Some call these drugs blood thinners. If you have a blood-clotting problem, BT may harm you.

Clinical study

In 2007, doctors studied nearly 300 patients who had severe asthma. In this study, they saw how well BT worked and what side effects patients had. Doctors treated about 200 people with BT. This was the "BT Group." Doctors treated another group in a similar way, but they did not heat their airways. This was the "Sham Group." Patients did not know which group they were in. Doctors studied these patients for a year after their last treatment. We do not know how well patients did beyond one year. This is still being studied.



What are the risks and side effects of BT?

Right after their doctors treated them, many patients in the study had side effects. **Table 1** shows how many people had each side effect. The table shows side effects that occurred in 3 or more in every 100 patients in the BT group.

How to read this table:

- Short-term: from start of first treatment until 6 weeks after third treatment.
- Long-term: from 6 weeks after last treatment until 1 year after last treatment.
- In the table, some patients had more than one side effect.
- Look at **Table 1**.
  - Think of a group of 100 patients.
  - Look at the column that says "Short-term period."
  - Go down that column to the row that reads "More than one symptom of asthma."
  - This row means that 52 out of every 100 patients in the BT Group had "more than one symptom of asthma" sometime after their first treatment until 6 weeks after their third treatment.
  - On the same row, now look at the "Long-term period" column.
  - You see there were 27 out of every 100 patients in the BT Group who had "more than one symptom of asthma" in the long-term period.
  - The 52 and the 27 are not separate groups of patients. Some patients may be counted in both groups:
    - One or more patients who had a "short-term period" effect may have also had a "long-term period" effect. Meaning he or she did not get better.
    - One or more patients who did not have a "short-term period" effect may have had a "long-term period" effect. Meaning he or she got worse later.
    - One or more patients who had a "short-term period" effect may not have had a "long-term period" effect. Meaning their problem went away.

Other side effects related to the lungs, ear, nose, and throat occurred in the short-term or long-term periods in the BT group. The following side effects occurred in 1 or more in every 100 patients in the BT group, but less often than the side effects in **Table 1**: abnormal breath sounds, acute swelling of the airways, blocked airways, bleeding during the procedure, bloody mucus, bloody nose, chest

Table 1: Short-term and Long-term side effects

	Short-term period		Long-term period	
Type of Side Effect	BT Group	Sham Group	BT Group	Sham Group
Related to Breathing	OUT OF EVERY 100 PATIENTS			
More than one symptom of asthma	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Shortness of breath	11	6	2	1
Chest discomfort	9	10	2	1
Infection in the lower airways	8	2	3	6
Productive cough	7	9	3	4
Collapse of part of the lung	5	0	0	0
Swelling of the airways	4	2	7	5
Bleeding	3	0	0	0
Related to Ear, Nose, and Throat				
Infection in the upper airways	20	11	30	26
Swelling of the nose and/or throat	5	7	11	5
Throat irritation	5	12	1	3
Infection in the upper airways caused by a virus	4	2	6	7
Sinusitis	3	5	6	7
Acute sinusitis	3	2	4	8
Sore throat	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
All Other				
Headaches	14	9	5	3
Back pain	5	6	3	5
Fever	4	2	0	1
Influenza	4	2	4	12
Upset stomach	4	2	2	4
Anxiety	4	0	1	2
Nausea	3	4	1	1
High blood pressure	3	2	3	3
Urinary tract infection	1	1	3	1

*One instance of bleeding occurred 31 days after a BT treatment and was treated with a medical procedure.

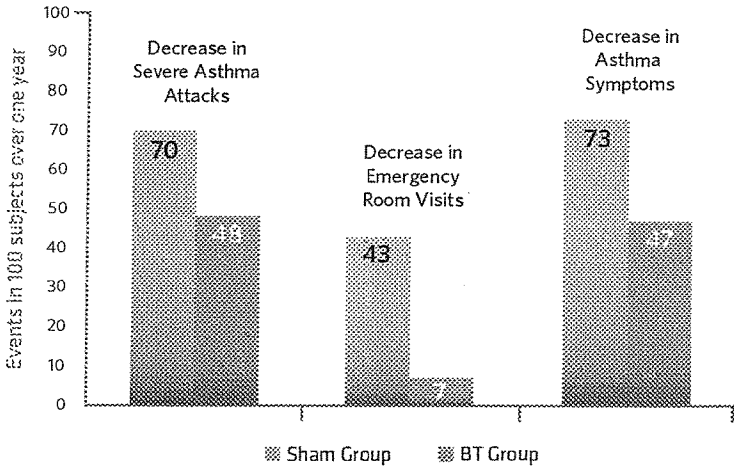
congestion, increased mucus in upper airways, infection in the lower airways caused by a virus, low oxygen in the blood, narrowing of airways, nasal congestion, pneumonia, runny nose, and swelling of the throat caused by a virus.

Ask your doctor about other uncommon side effects that are not related to the lungs, ear, nose, and throat.

What are the benefits of BT?

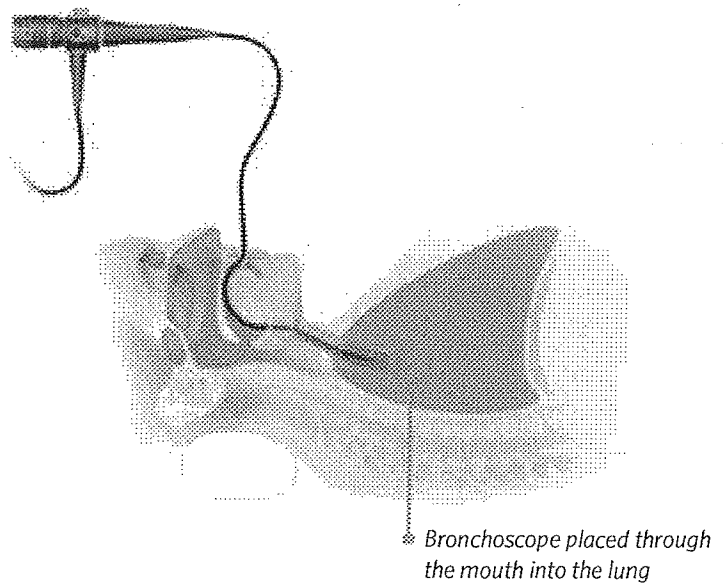
The study showed that the people in the BT Group had fewer severe asthma attacks, visits to the emergency room, and asthma symptoms, as shown in **Figure 2**.

Figure 2. Benefits of BT



The BT Group also lost on average 3 fewer days per patient from work, school, or other daily activities due to asthma symptoms. This was for one year after treatment compared to the Sham Group. This is not shown in **Figure 2**.

Figure 3. Placement of bronchoscope into your lungs

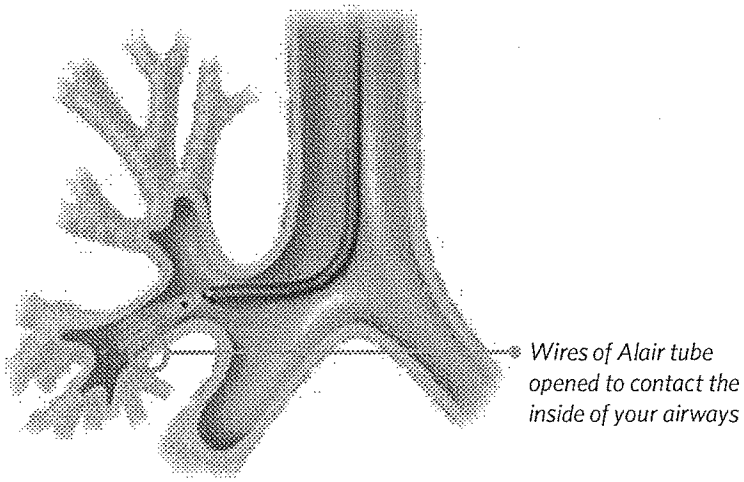


What will happen if you decide to have the BT treatment for your severe asthma?

- There will be 3 treatments. There will be 3 weeks in between each treatment.
- You will prepare for each treatment by taking a 50 mg steroid pill by mouth once a day for 3 days before the treatment.
- You will also take a 50 mg steroid pill on the day of the treatment.
- On each BT treatment day, your doctor will test your lungs. He or she will do this by checking how much air you can blow out.
- Your doctor will make sure you don't have an infection. An infection would delay the treatment.
- Your doctor will tell you what he or she will do during BT.
- Your doctor will:

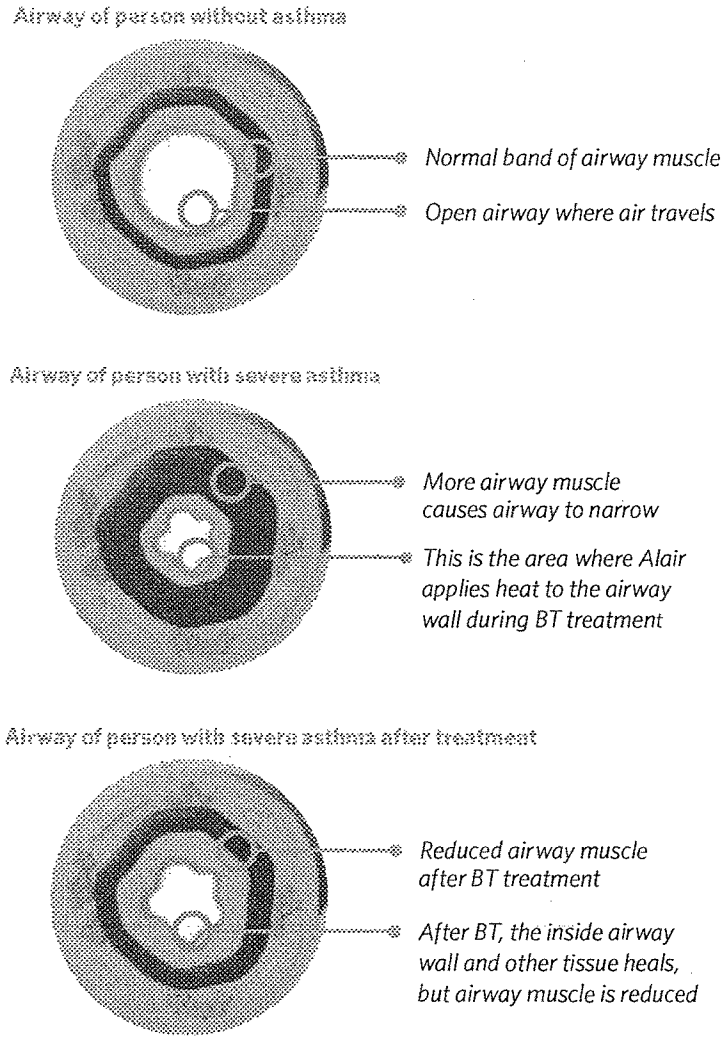
  1. Give you medicine to make you sleepy.
  2. Put a small tube called a bronchoscope through your mouth into your airways. See **Figure 3**.
  3. Put the smaller Alair™ tube through the bronchoscope. The wires on its end will touch your airways. See **Figure 4**.

Figure 4. Placement of Alair tube in your lungs



4. Heat the wires on the end of the small Alair™ tube to reduce some of the airway muscle tissue. You won't feel this because your doctor gave you medicine. See **Figure 5** for how airways look before and after Bronchial Thermoplasty treatment.

Figure 5. Airways before and after BT treatment



5. Move the small Alair tube to more places and treat them the same way.
6. Take the small Alair tube and the bronchoscope out.
7. Watch over you as you wake up and recover.

What happens after each BT treatment?

- You need to take a 50 mg steroid pill the day after.
- Your doctor will contact you by phone to check on you:
  - The day after your treatment
  - The day after that, and
  - A week after your treatment
- You will still need to take your asthma medicine.

After your airways heal from your first treatment, you will go back to your doctor for your second treatment. Your doctor will treat more of your airways. After you get well from that, your doctor will treat the rest of your airways in your third treatment.

Use your rescue inhaler if your asthma symptoms get bad. Tell your doctor if you needed to use your rescue inhaler.

When to call the doctor?

If you have this treatment, contact your doctor if your asthma symptoms get worse and do not get better after using your rescue inhaler.

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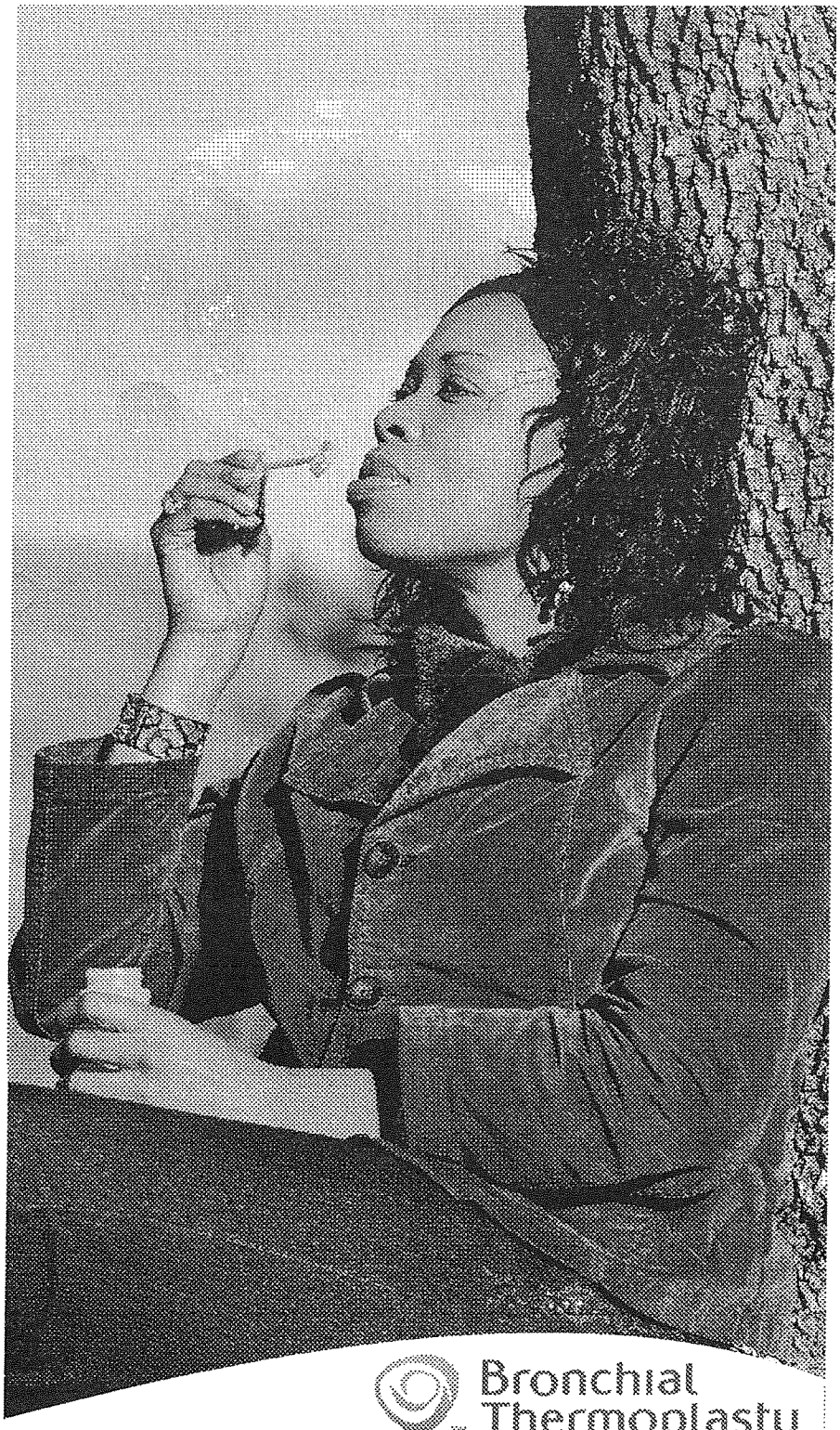


Bronchial Thermoplasty

DELIVERED BY THE ALAIR® SYSTEM

A New Procedure for Severe Asthma in Adults

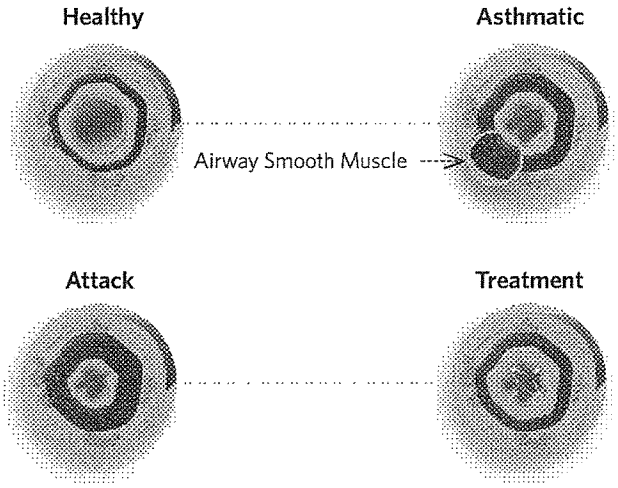
Bronchial Thermoplasty Provides Asthma Control 365 Days a Year

Bronchial thermoplasty (BT) is a non-drug procedure for severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists such as Advair®, Symbicort® and Dulera®.

How it Works

The Alair® Bronchial Thermoplasty System (the "Alair® System") delivers thermal energy to the airway wall in a precisely controlled manner in order to reduce excessive airway smooth muscle (ASM). Reducing airway smooth muscle decreases the ability of the airways to constrict, thereby reducing the frequency of asthma attacks.

Airway Cross Sections



The BT Procedure

BT is a minimally invasive bronchoscopic procedure performed in three outpatient procedure visits, each treating a different area of the lungs and scheduled approximately three weeks apart. After all three procedures are performed, the bronchial thermoplasty treatment is complete.

BT Complements Asthma Medications

BT is expected to complement current asthma maintence medications by providing long-lasting asthma control and improving asthma-related quality of life of patients with severe asthma.

BT Benefits and Risks

One year follow-up indicates...

Benefits of BT

- 32 % reduction in asthma attacks
- 84 % reduction in emergency room visits for respiratory symptoms
- 73 % reduction in hospitalizations for respiratory symptoms
- 66 % reduction in days lost from work/school/ other daily activities due to asthma
- Improved asthma quality of life
- Stable safety profile observed out to 5 years

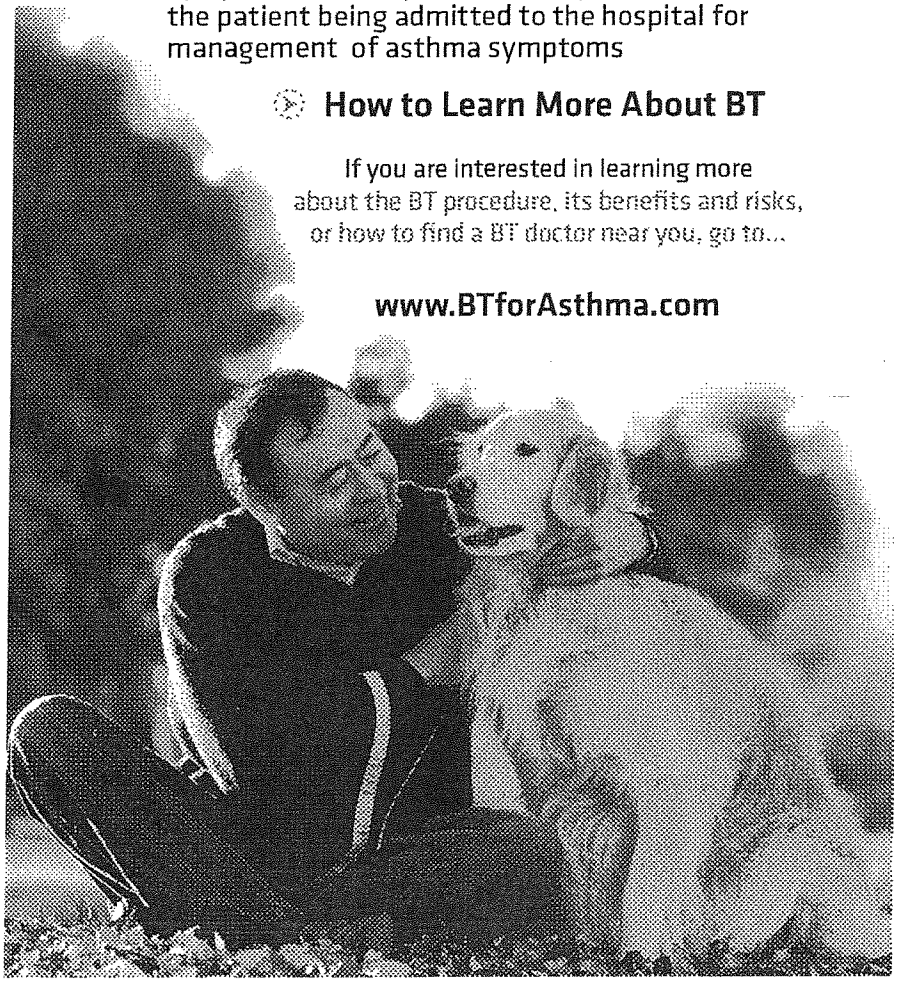
Risks of BT?

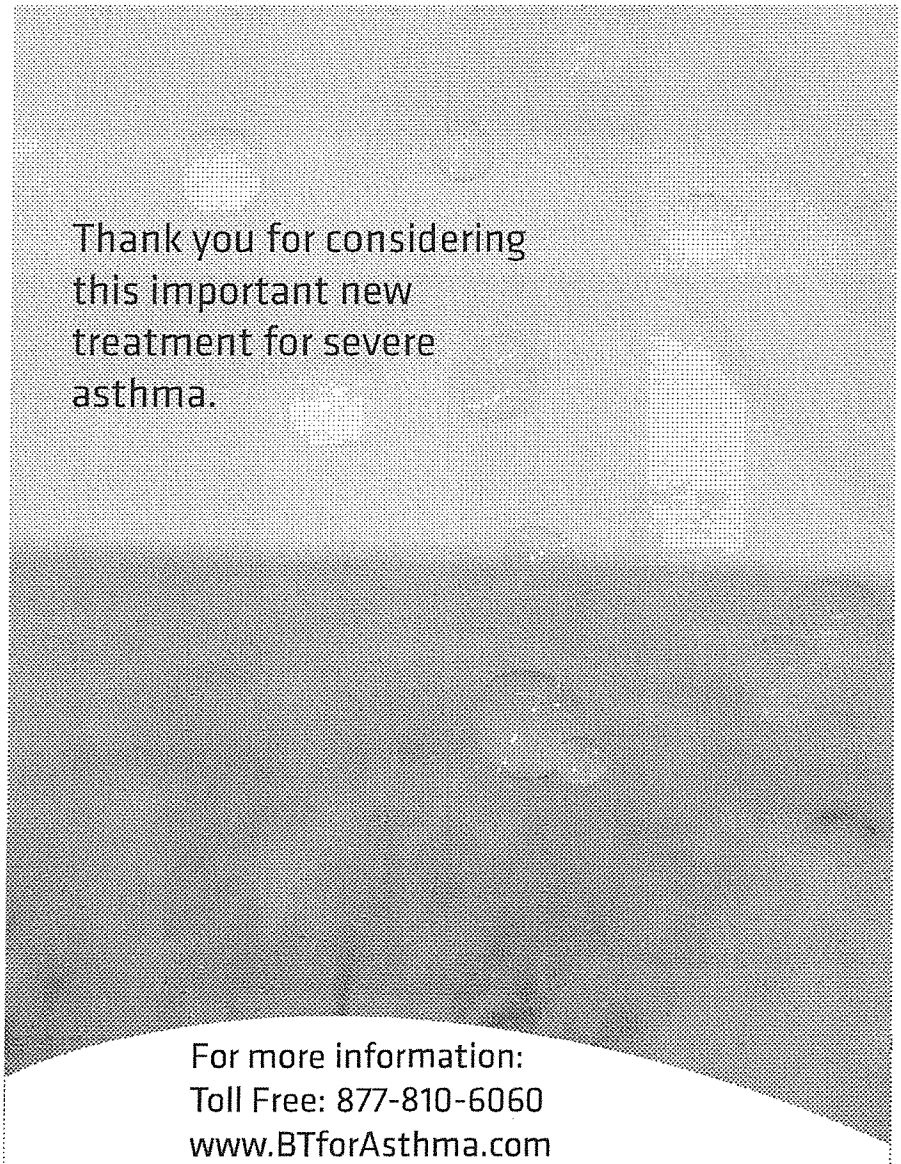
- In the period immediately following BT, there is an expected increase and worsening of asthma -related respiratory symptoms
- These events typically occur within a day of the procedure and resolve on average within seven days with standard care
- There is a small possibility (3.4% per procedure) that the temporary worsening of asthma symptoms after a procedure may result in the patient being admitted to the hospital for management of asthma symptoms

How to Learn More About BT

If you are interested in learning more about the BT procedure, its benefits and risks, or how to find a BT doctor near you, go to...

www.BTforAsthma.com





For more information:
Toll Free: 877-810-6060
www.BTforAsthma.com

Asthmatx
A Boston Scientific Company

Asthmatx Inc.
888 Ross Drive, Suite 100
Sunnyvale, CA 94089

www.asthmatx.com

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10-090 Rev. B

New Procedure for Asthma

Every Minute Hour Transformed.

days a year.

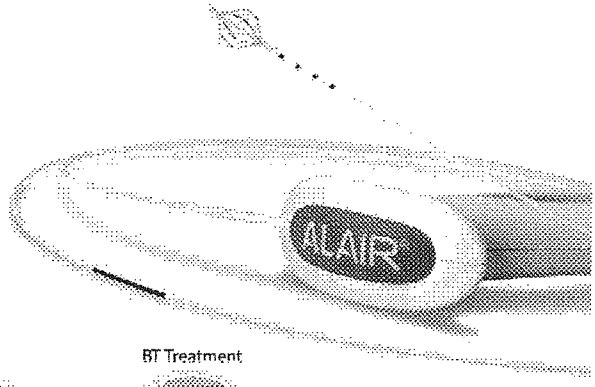
A Procedure for Long Lasting Control of Severe Asthma, **365 Days a Year.**

Bronchial Thermoplasty™
DELIVERED BY THE ALAIR® SYSTEM

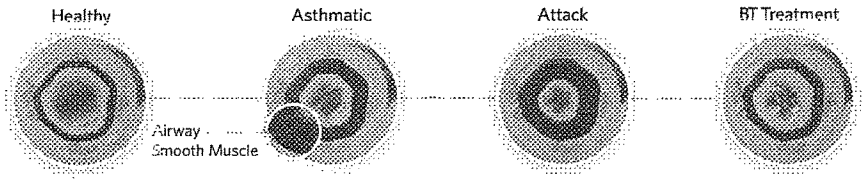
Ask your doctor about...

Bronchial Thermoplasty for Treatment of Severe Asthma in Adults

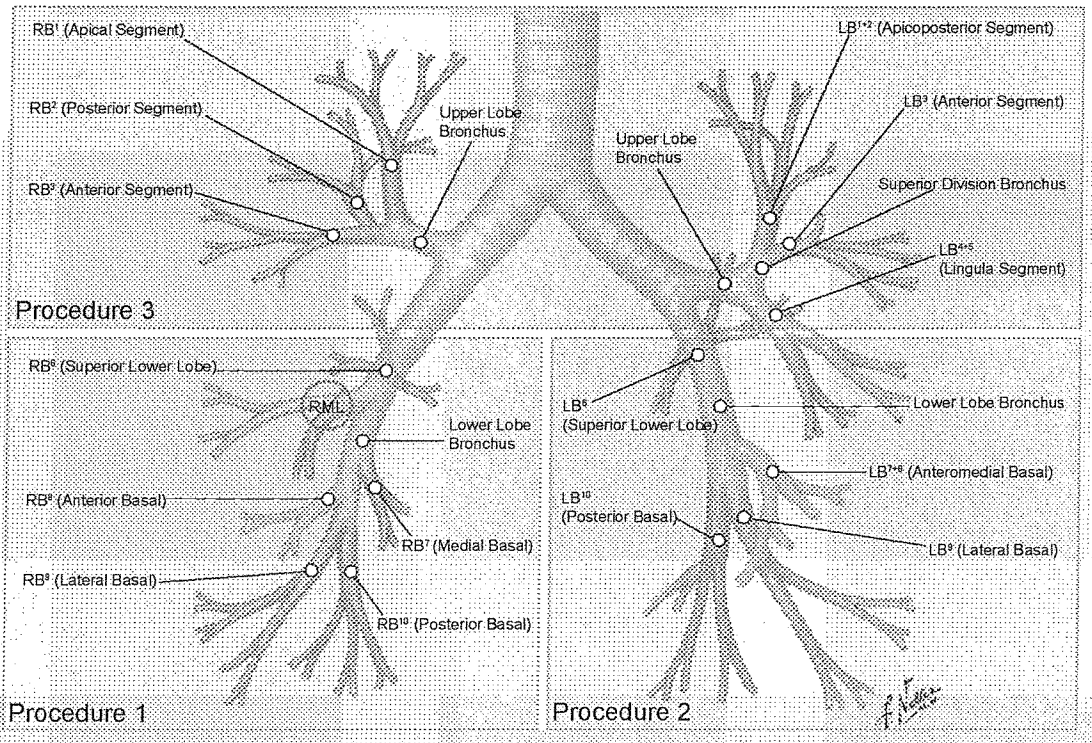
Bronchial thermoplasty (BT) is an outpatient, bronchoscopic procedure that delivers precisely controlled thermal energy to reduce excess airway smooth muscle that is associated with airway constriction in patients with asthma. **BT is indicated for use in adults 18 and over with severe asthma not well controlled with available medication.**



Airway Cross Section



BT Procedure Lung Map



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10-035 Rev. B

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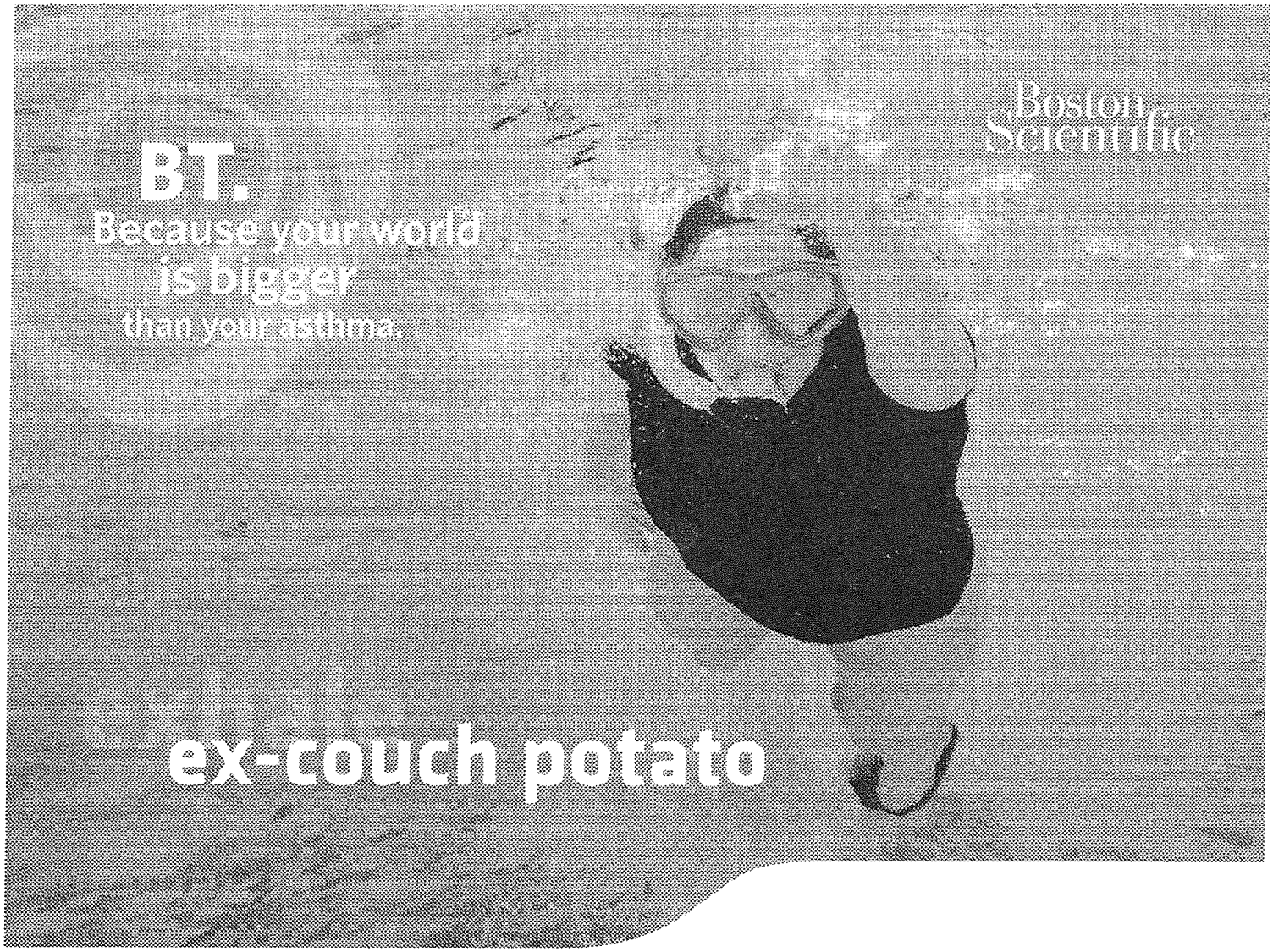

It's not a medication.
It's revolutionary and long-lasting relief for severe asthma.

If asthma is limiting your options, perhaps it's time to look beyond medication alone. Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe outpatient procedure clinically proven to provide a long-lasting reduction in asthma attacks for patients with severe asthma, with benefits maintained out to 5 years.[1] Fewer asthma attacks means less need for the associated oral steroid treatment—and its side effects.

In addition, BT provided a significant improvement in asthma-related quality of life for 79% of patients.[2]

Request your FREE DVD and learn more at BTforAsthma.com/living.

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NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

References: 1. Wechsler M, et al; for the AIR2 Trial Study Group [published ahead of print September, 2013]. *J Allergy Clin Immunol.* doi:10.1016/j.jaci.2013.08.009. **2.** Castro M. et al, for the AIR2 Trial Study Group. *Ann Allergy Asthma Immunol.* 2011;107:65-70.

BSC000586

Thank you for considering this important new treatment for severe asthma.

www.BTforAsthma.com

Where to learn more about the Alair® System and BT

- Contact your doctor, or
- Call:

Boston Scientific
Toll Free: 877 810 6060

[illegible]

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Boston Scientific Corporation
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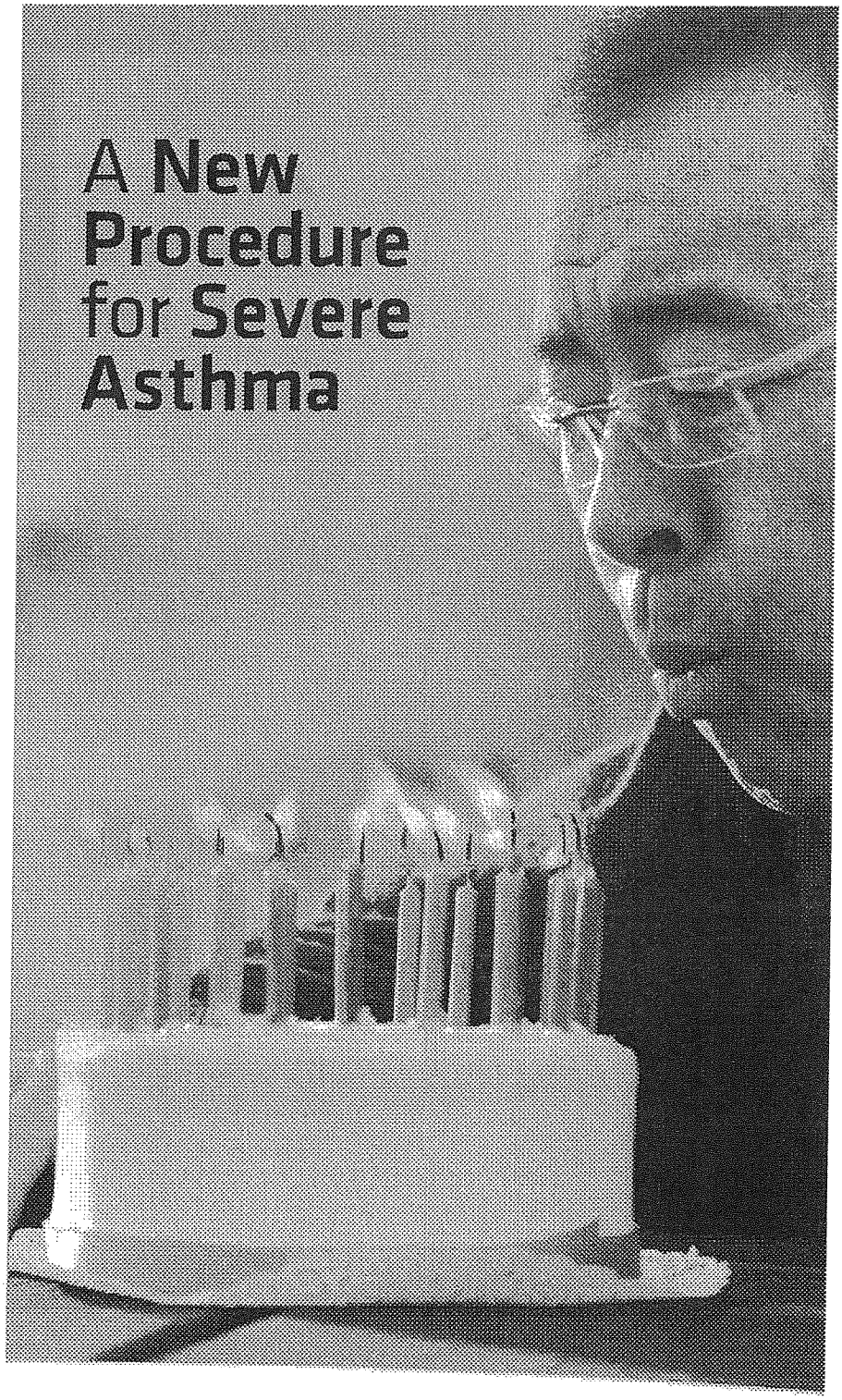
Sunnyvale, CA 94089

www.BTforAsthma.com



This brochure describes a new procedure for treating severe asthma in adults.

Bronchial Thermoplasty

DELIVERED BY THE ALAIR® SYSTEM

Contents

About Severe Asthma

What happens when you have severe asthma?

Air travels in and out of your lungs through airways, which are tubes. There are tiny muscles in the walls of the airways. People who have severe asthma have larger muscles in their airways than other people. The airways close down when these muscles contract.

What happens when your airways close down?

When airways close down it can be harder to breathe. Your chest may feel tight. You may wheeze or cough. Asthma medicines usually open up the airways. These medicines do not always work well in patients who have severe asthma.

Why do doctors do this treatment?

You have severe asthma. Your asthma is severe because the asthma drugs you take now do not control your asthma symptoms.

Your doctor wants to use the Alair® System to treat your severe asthma. This treatment is called Bronchial Thermoplasty (BT). BT is a procedure and not an asthma medicine. Your doctor thinks your health is good enough to have this treatment.

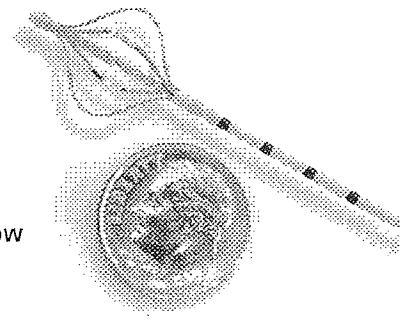
If you decide to have this treatment, you will need to do what your doctor asks you to do or you may be harmed.

What is the Alair® System?

The Alair® System is the tool that your doctor will use to perform BT. The Alair® System has two main parts:

- A small tube with 4 wires at the end. See Figure 1.

Figure 1: Actual size of tip of Alair tube



- A machine that heats the wires

You need to decide if BT is right for you. You will be treated by a doctor who has been trained and knows how to use it correctly.

Who

What is Bronchial Thermoplasty?

The Alair® System mildly heats your airway walls. This heating reduces some of the extra muscle present in the airways. This may allow your airways to stay more open and help you breathe better.

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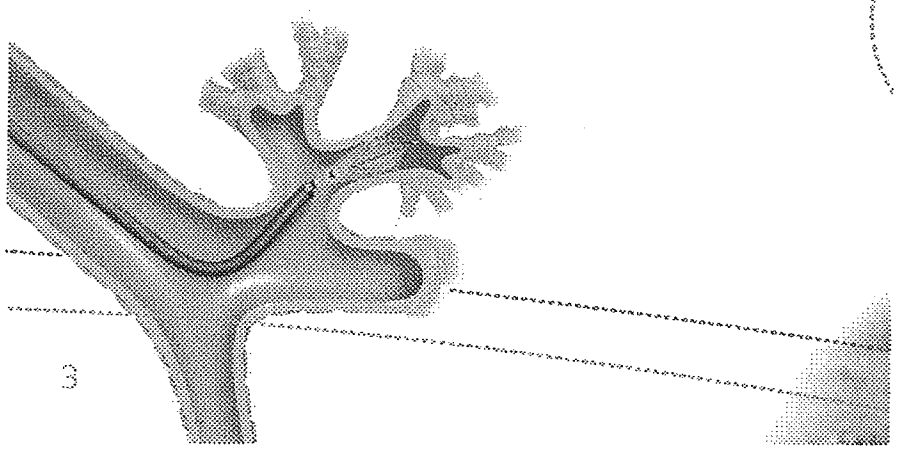
- You cannot have this treatment if you are less than 18 years old. No one has tested BT in patients younger than 18 years.



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- A blood clotting problem. Tell your doctor if you take any drugs to keep your blood from clotting. Some call these drugs blood thinners. If you have a blood clotting problem, BT may harm you.

Clinical Study

In 2007, doctors studied nearly 300 patients who had severe asthma. In this study, they saw how well BT worked and what side effects patients had. Doctors treated about 200 people with BT. This was the "BT Group". Doctors treated another group in a similar way, but they did not heat their airways. This was the "Sham Group". Patients did not know which group they were in. Doctors studied these patients for a year after their last treatment. We do not know how well patients did beyond one year. This is still being studied.

Risks

What are the risks and side effects of BT?

Right after their doctors treated them, many patients in the study had side effects. Table 1 shows how many people had each side effect. The table shows side effects that occurred in 3 or more out of every 100 patients in the BT group.

How to read this table:

- Short Term: from start of first treatment until 6 weeks after third treatment.
- Long Term: from 6 weeks after last treatment until 1 year after last treatment.
- In the table, some patients had more than one side effect.
- Look at Table 1.
  - Think of a group of 100 patients.
  - Look at the column that says "Short Term Period".
  - Go down that column to the row that reads "more than one symptom of asthma."
  - This row means that 52 out of every 100 patients in the BT Group had "more than one symptom of asthma" sometime after their first treatment until 6 weeks after their third treatment.
  - On the same row, now look at the "Long Term Period" column.
  - You see there were 27 out of every 100 patients in the BT Group who had "more than one symptom of asthma" in the long term period.
  - The 52 and the 27 are not separate groups of patients. Some patients may be counted in both groups:
    - One or more patients who had a "Short Term Period" effect may have also had a "Long Term Period" effect. Meaning he or she did not get better.
    - One or more patients who did not have a "Short Term Period" effect may have had a "Long Term Period" effect. Meaning he or she got worse later.
    - One or more patients who had a "Short Term Period" effect may not have had a "Long Term Period" effect. Meaning their problem went away.

Other side effects related to the lungs, ear, nose and throat occurred in the Short Term or Long Term Periods in the BT group. The following side effects occurred in 1 or more out of every 100 patients in the BT group, but less often than the side effects in Table 1: abnormal breath sounds, acute swelling of the airways, blocked airways, bleeding during the procedure, bloody mucus, bloody nose, chest

Table 1: Short Term and Long Term Side Effects

Type of Side Effect	Short-Term Period		Long-Term Period	
	BT Group	Sham Group	BT Group	Sham Group
Related to Breathing	OUT OF EVERY 100 PATIENTS			
More than one symptom of asthma	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Shortness of breath	11	6	2	1
Chest discomfort	9	10	2	1
Infection in the lower airways	8	2	3	6
Productive cough	7	9	3	4
Collapse of part of the lung	5	0	0	0
Swelling of the airways	4	2	7	5
Bleeding	3	0	0	0
Related to Ear, Nose and Throat				
Infection in the upper airways	20	11	30	26
Swelling of the nose and/or throat	5	7	11	5
Throat irritation	5	12	1	3
Infection in the upper airways caused by a virus	4	2	6	7
Sinusitis	3	5	6	7
Acute Sinusitis	3	2	4	8
Sore throat	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
All Other				
Headaches	14	9	5	3
Back pain	5	6	3	5
Fever	4	2	0	1
Influenza	4	2	4	12
Upset stomach	4	2	2	4
Anxiety	4	0	1	2
Nausea	3	4	1	1
High blood pressure	3	2	3	3
Urinary tract infection	1	1	3	1

*One instance of bleeding occurred 31 days after a BT treatment and was treated with a medical procedure.

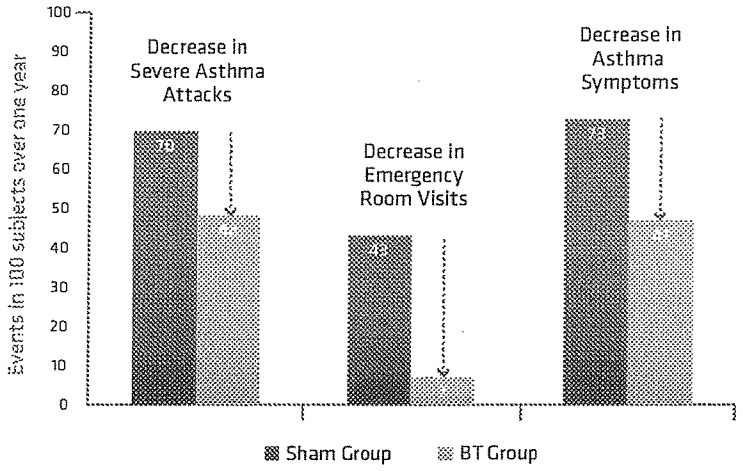
congestion, increased mucus in upper airways, infection in the lower airways caused by a virus, low oxygen in the blood, narrowing of airways, nasal congestion, pneumonia, runny nose, and swelling of the throat caused by a virus.

Ask your doctor about other uncommon side effects that are not related to the lungs, ear, nose and throat.

What are the benefits of BT?

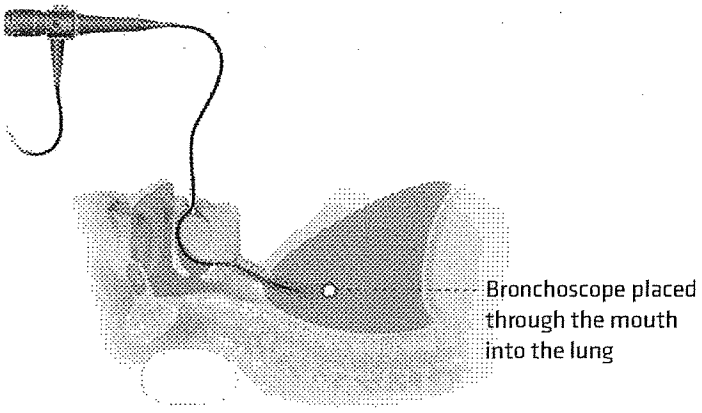
The study showed that the people in the BT Group had fewer severe asthma attacks, visits to the emergency room, and asthma symptoms as shown in Figure 2.

Figure 2 Benefits of BT



The BT Group also lost on average 3 fewer days per patient from work, school, or other daily activities due to asthma symptoms. This was for one year after treatment compared to the Sham Group. This is not shown in Figure 2.

Figure 3. Placement of Bronchoscope into your lungs

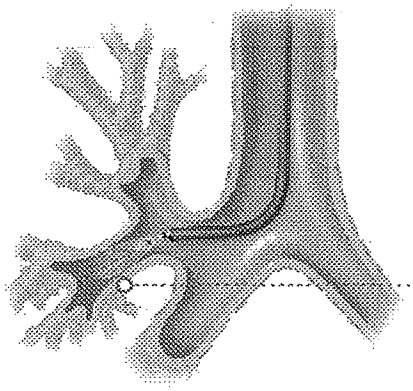


What will happen if you decide to have the BT treatment for your severe asthma?

- There will be 3 treatments. There will be 3 weeks in between each treatment.
- You will prepare for each treatment by taking a 50-mg steroid pill by mouth once a day for 3 days before the treatment.
- You will also take a 50-mg steroid pill on the day of the treatment.
- On each BT treatment day, your doctor will test your lungs. He or she will do this by checking how much air you can blow out.
- Your doctor will make sure you don't have an infection. An infection would delay the treatment.
- Your doctor will tell you what he or she will do during BT.
- Your doctor will:

1. Give you medicines to make you sleepy.
2. Put a small tube called a bronchoscope through your mouth into your airways. See Figure 3.
3. Put the smaller Alair tube through the bronchoscope. The wires on its end will touch your airways. See Figure 4.

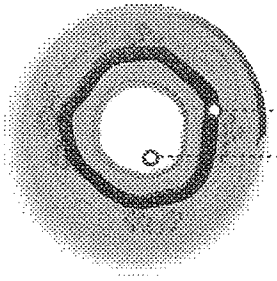
Figure 4. Placement of Alair tube in your lungs



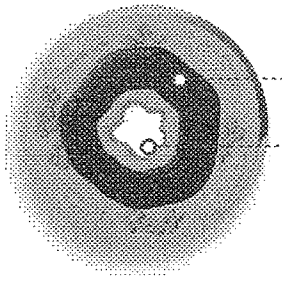
4. Heat the wires on the end of the small Alair tube to reduce some of the airway muscle tissue. You won't feel this because your doctor gave you medicines. See Figure 5 for how airways look before and after BT treatment.

Figure 5. Airways Before and After BT Treatment

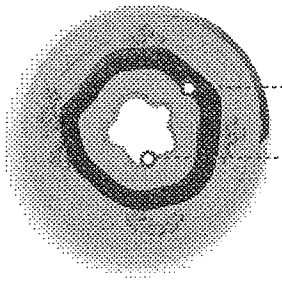
Airway of Person without Asthma



Airway of Person with Severe Asthma



Airway of Person with Severe Asthma after Treatment



5. Move the small Alair tube to more places and treat them the same way.
6. Take the small Alair tube and the bronchoscope out.
7. Watch over you as you wake up and recover.

What happens after each BT treatment?

- You have to take a 50-mg steroid pill the day after.
- Your doctor will contact you by phone to check on you:
  - The day after your treatment
  - The day after that, and
  - A week after your treatment
- You will still have to take your asthma medicine.

After your airways heal from your first treatment, you will go back to your doctor for your second treatment. Your doctor will treat more of your airways. After you get well from that, your doctor will treat the rest of your airways in your third treatment.

Use your rescue inhaler if your asthma symptoms get bad. Tell your doctor if you needed to use your rescue inhaler.

When to call the doctor?

If you have this treatment, contact your doctor if your asthma symptoms get worse and do not get better after taking your rescue inhaler.

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events:

The Alair® Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The Alair® System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair® System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms.

New Procedure for Asthma

Living with asthma. Transformed.

days a year.

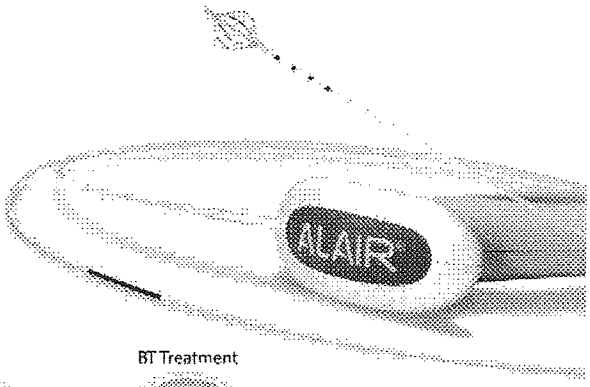
A Procedure for Long Lasting Control of Severe Asthma, **365 Days a Year.**

Bronchial Thermoplasty™
DELIVERED BY THE ALAIR® SYSTEM

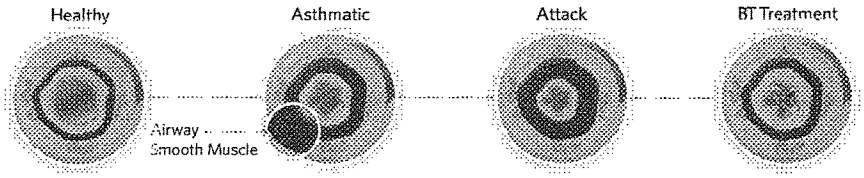
Ask your doctor about...

Bronchial Thermoplasty for Treatment of Severe Asthma in Adults

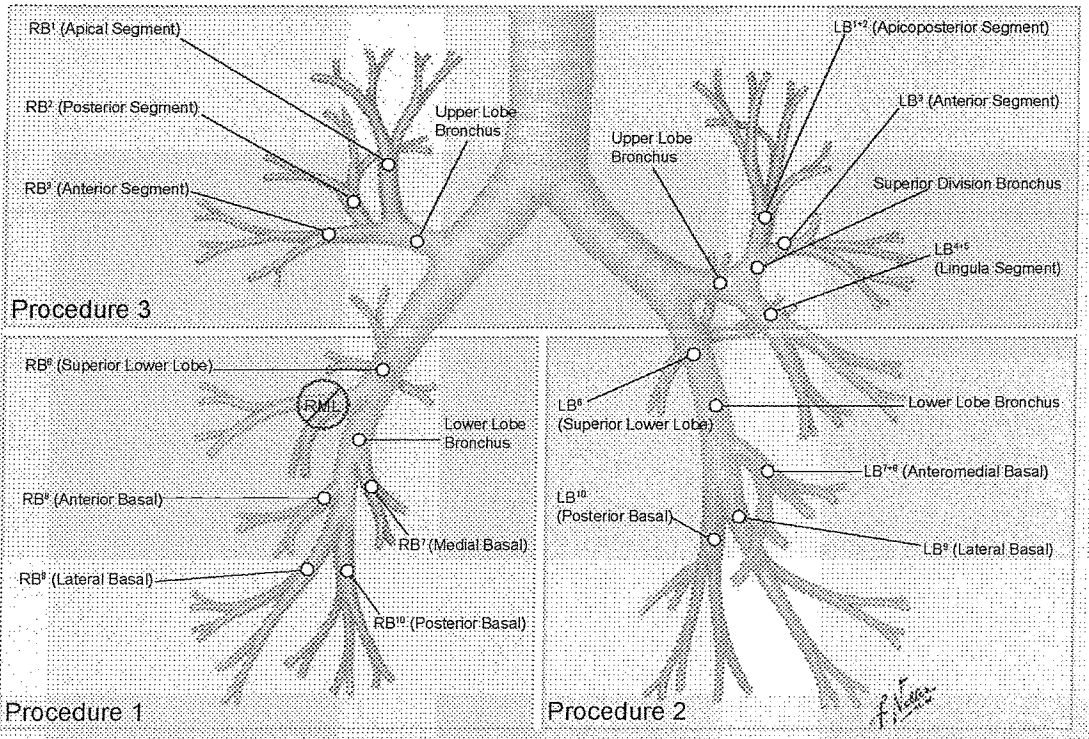
Bronchial thermoplasty (BT) is an outpatient, bronchoscopic procedure that delivers precisely controlled thermal energy to reduce excess airway smooth muscle that is associated with airway constriction in patients with asthma. **BT is indicated for use in adults 18 and over with severe asthma not well controlled with available medication.**



Airway Cross Section



BT Procedure Lung Map



Asthmatx
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For more information visit www.BTforAsthma.com

10-035 Rev. B

BSC000697

Bronchial Thermoplasty—
Long-lasting benefits clinically proven
for patients with severe asthma

NEW 5 YEAR DATA

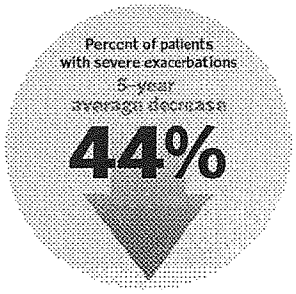
In the **Asthma Intervention Research 2 (AIR2) Trial**, one of the largest sham-controlled medical device trials in pulmonary medicine, patients with severe asthma showed significant improvement compared to sham-controlled patients 1 year after treatment with Bronchial Thermoplasty (BT) delivered by the Alair™ System. The **AIR2 Trial 5-Year Extension Study** evaluated the sustained effectiveness and safety of BT out to 5 years in BT-treated patients from the AIR2 Trial.[1,2]

Fewer exacerbations, with effectiveness maintained out to 5 years

- 32% decrease in severe asthma exacerbations (requiring systemic corticosteroids) at 1 year compared with sham-controlled patients[1]
- Reduction in percentage of patients experiencing exacerbations seen at 1 year maintained out to 5 years (primary endpoint)[2]

Additionally, 48% decrease (average over 5 years) in the rate of severe exacerbations, compared with 12 months prior to BT treatment[2]

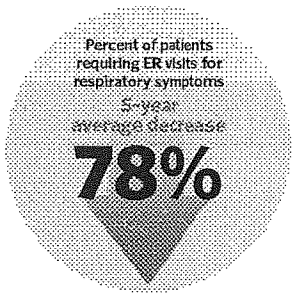
- The decrease in severe exacerbations over 5 years included a substantial reduction in the use of systemic corticosteroids to treat those exacerbations[2]
- Fewer asthma exacerbations means reduced need for the associated oral steroid treatment and its side effects



Fewer emergency room visits, with effectiveness maintained out to 5 years

- 84% reduction in emergency room visits for respiratory symptoms at 1 year compared to sham-controlled patients[1]
- Reduction in ER visits seen at 1 year maintained out to 5 years[2]

Additionally, 88% decrease (average over 5 years) in the rate of ER visits for respiratory symptoms, compared with 12 months prior to BT treatment[2]



n = 162 (85% retention rate at Year 5)

View the 5-year clinical trial results at BTat5years.com

***NOW AVAILABLE** from Boston Scientific*
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

BSC000698

"BT has become an important addition to our treatment armamentarium for patients with severe persistent asthma who remain symptomatic despite taking ICS and LABA."

— Wechsler M, et al. *Journal of Allergy and Clinical Immunology.* 2013.

Bronchial Thermoplasty—

Established, long-term effectiveness and safety in the treatment of severe asthma

Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe and minimally invasive outpatient procedure clinically proven to provide a long-lasting reduction in asthma exacerbations and respiratory-related ER visits for patients with severe asthma. Additional benefits include:

Quality-of-life improvement

- 79% of patients who were treated with BT reported a significant improvement in their asthma-related quality of life[1]

Fewer absences

- 66% fewer asthma-related days lost from work, school, and other activities at 1 year compared with sham-controlled patients[1]

Long-term safety maintained out to 5 years

- No increase in hospitalizations, asthma symptoms, or respiratory adverse events over the course of 5 years[2]
- No structural changes in airways that were clinically significant were due to BT at 5 years (based on high-resolution CT review)[2]
- No clinically significant deterioration in lung function (FEV_1) at 5 years[2]

As with any procedure, there are risks, and individual results may vary. The most common adverse event of BT is a temporary worsening of respiratory-related symptoms. These events typically occur within one day of the BT procedure and usually resolve within a week with standard care. There is a small risk (3.4% per procedure) that symptoms may require hospitalization.

View the 5-year clinical trial results at BTat5years.com

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events: The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. The Alair System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair System. Patients should be stable and suitable to undergo bronchoscopy. The most common adverse event of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms. Rx only.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions, and warnings can be found with product labeling.

References: 1. Castro M, et al; for the AIR2 Trial Study Group. *Am J Respir Crit Care Med.* 2010;181:116-124. **2.** Wechsler M, et al; for the AIR2 Trial Study Group [published ahead of print September, 2013]. *J Allergy Clin Immunol.* doi:10.1016/j.jaci.2013.08.009.

***NOW AVAILABLE** from Boston Scientific*
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

BSC000699

NEW 5 YEAR DATA

Established long-term effectiveness and safety

Newly published data confirm Bronchial Thermoplasty (BT), delivered by the Alair™ System, as a safe and minimally invasive procedure that provides a long-term reduction in asthma exacerbations for patients with severe asthma.

Fewer respiratory-related emergency room visits

- **84% reduction in emergency room visits** for respiratory symptoms at 1 year compared with sham-controlled patients, with reduction maintained out to 5 years[1,2]

Fewer exacerbations, with effectiveness maintained out to 5 years

- **32% decrease in severe asthma exacerbations** (requiring systemic corticosteroids) at 1 year compared with sham-controlled patients, with reduction maintained out to 5 years[1,2]
  - —The decrease in severe exacerbations over 5 years included a substantial reduction in the use of systemic corticosteroids associated with those exacerbations[2]
- No increase in hospitalizations, asthma symptoms, or respiratory adverse events over 5-year period[2]

View the 5-year clinical trial results at BT5years.com

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events: The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. The Alair System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair System. Patients should be stable and suitable to undergo bronchoscopy. The most common adverse event of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms. Rx only.

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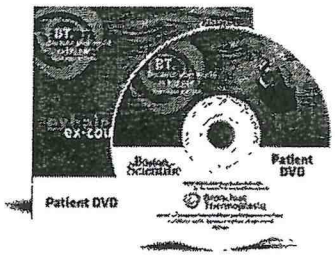
NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults

Bronchial Thermoplasty™

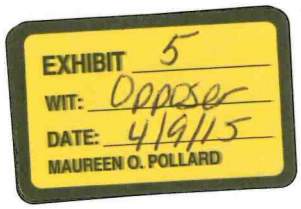
Start your BT journey with a FREE DVD and continued support

Ready for a bigger world with fewer asthma attacks?

Complete the fields below to request your **FREE DVD** and connect with the BT 1-2-3 Support Program



Thank you for your interest in Bronchial Thermoplasty (BT). Your requested information is on its way to you. In the meantime, we invite you to explore the BTforAsthma.com website to learn more about this revolutionary procedure. If you have questions about BT, talk to your doctor or call our patient support line at 1-877-810-6060.



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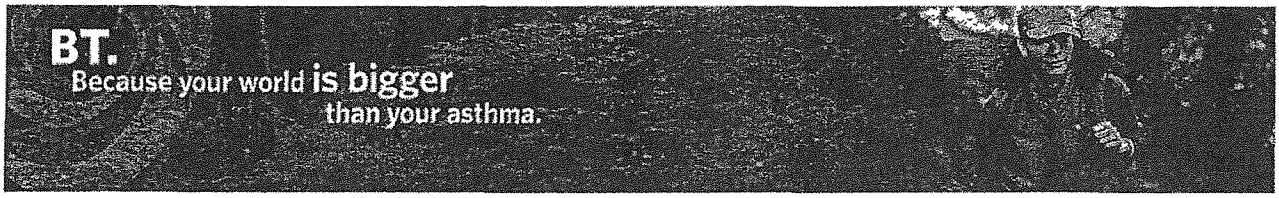
BSC Privacy Policy



Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Home > Are you a BT candidate? > Are you a BT candidate?

Are you a BT candidate?

You may be eligible for Bronchial Thermoplasty (BT) treatment if:

You are 18 years or older with severe asthma, AND

You have asthma symptoms despite taking inhaled corticosteroids and long-acting beta-agonists such as Advair™, Dulera™, or Symbicort™.

Take the Asthma Impact Survey to discover more about how asthma symptoms may be affecting your life.

You are not a candidate for BT if:

You have a pacemaker, internal defibrillator, or other implantable electronic device.

You have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines.

You've been treated previously with BT.

Who performs the BT procedure?

BT is performed by a specially trained pulmonologist. If your regular doctor currently managing your asthma is an allergist, family practice physician, general practitioner, internist or other physician, he or she will be able to refer you to a BT Clinic for a consultation with a pulmonologist. After your BT treatment is completed, you will return to your regular asthma doctor to manage your asthma.

For help with discussing this treatment with your doctor:

Complete the Asthma Impact Survey.

Share your survey results with the physician who manages your asthma.

Learn more about BT with this FREE DVD for patients with asthma.

"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.

Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Home > Are you a BT candidate? > Take the Asthma Impact Survey

How much does asthma affect your quality of life?

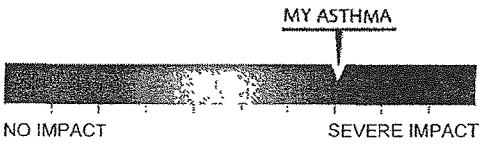
See for yourself: If asthma is limiting the choices you make in life, perhaps it's time to look beyond medication alone. The following survey was created by a doctor and can help you recognize the many ways severe asthma may be affecting your life.

Be sure to share your answers with your doctor—and discover how Bronchial Thermoplasty (BT) may help you live a fuller life. BT, delivered by the Alair™ System, is not another medication—it's a revolutionary and safe procedure proven to provide a long-lasting reduction in asthma attacks.[1]

THE ASTHMA IMPACT SURVEY™

Congratulations on taking an important step toward a new life with fewer asthma attacks

Your responses indicate that asthma has a
severe impact
on your quality of life



Print my Survey results and letter to my doctor here.

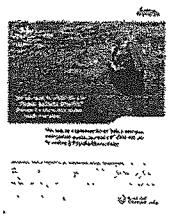
This survey is a diagnostic tool to assess the impact asthma has on your daily lifestyle. You should check with your doctor to make sure that you are taking your medication appropriately and consistently. Your medication dosage may need to be adjusted to help provide better symptom control. If you are taking the maximum tolerated medication regularly and continue to have asthma symptoms that impact your daily life, you may be a candidate for the BT treatment and you should consult an asthma specialist to learn more about your options.

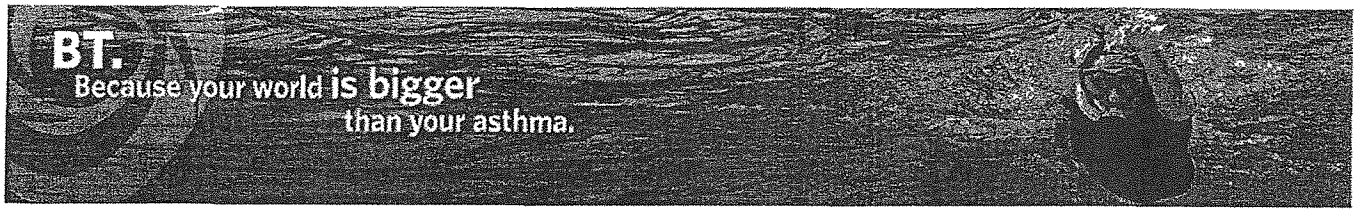
Take this survey and the letter with you to your doctor. It will help your doctor determine whether you might be a candidate for BT.

References

1. Wechsler M, et al, for the AIR2 Trial Study Group. *J Allergy Clin Immunol.* 2013;132.1295-1302.

Learn more about BT with this FREE DVD for patients with asthma.





US availability

International Availability

Find a BT Clinic

Type in your zip code or click on a state on the US map to see a list of physicians offering Bronchial Thermoplasty (BT) in that state.

Boston Scientific maintains an updated list of physicians who are trained to perform BT. The list is based upon location only.

http://www.btforasthma.com/find-clinic/physician-locator

If there isn't a BT Clinic in your area, contact Boston Scientific.

Not in the United States? View a list of hospitals outside of the US with BT Clinics

(* Required)

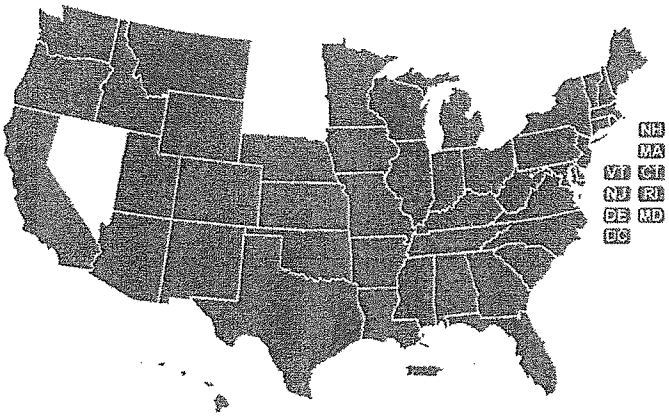
Zip Code: *

How far are you willing to travel? * 50 miles

Search

OR

Find Physicians in your state: Select



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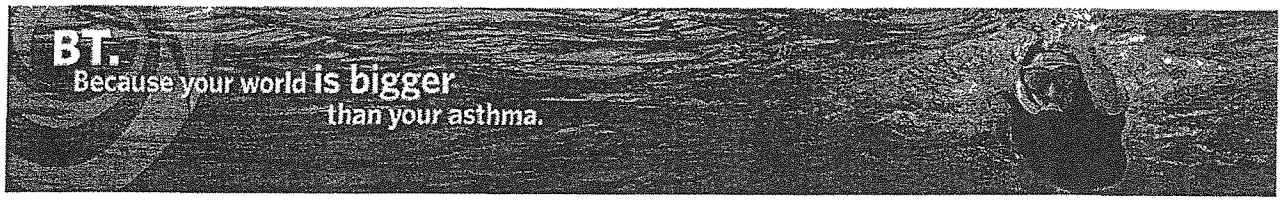
ENDO-142305-AE April 2014



Patient stories

Physician stories

In the news

Press releases

Real people, real results

Listen and watch as people with severe asthma discuss the dramatic difference Bronchial Thermoplasty (BT) has made in their lives.

Please note that individual BT treatment results may vary. BT is an add-on therapy that supplements your current asthma medications. BT, delivered by the Alair™ System, is

indicated for the treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

VIEW VIDEO

Angel's Story

"I've been able to cut the grass. I've been able to work on my car. I wasn't able to travel. I've been able to travel, something I haven't done for years."

VIEW VIDEO

Laretta's Story

"Now I can live life and go and do those fun activities that I hadn't done before. If you really want to live life and you really don't want a disease that's controlling your life or defining you, have BT."

VIEW VIDEO

Mike's and Jenny's Story

"I just feel like I'm free... I feel like the sky's the limit."

VIEW VIDEO

Chris's Story

"It was a moment of revelation. It's that sun breaking through the clouds and you go, 'It worked.'"

VIEW VIDEO

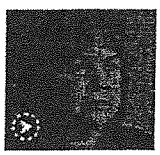
Debbie's Story

"I noticed doing things around the house, things that I would get out of breath with before. Like carrying up laundry from the basement, just something as simple as that... I wasn't as winded."

VIEW VIDEO

John's Story

"I've gone from torture to being able to live my life, I feel like I've got a second chance."

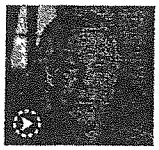


VIEW VIDEO

Brenda's Story

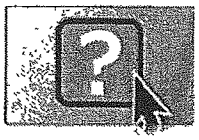
"I would highly recommend this to somebody else. It's just a simple procedure and it's a great benefit."

Jeff's Story



"My life has changed due to the treatment in a way that I'm not afraid to go hiking in the mountains."

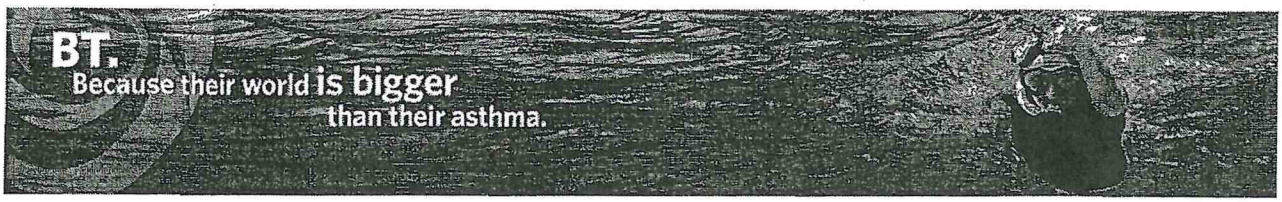
VIEW VIDEO



How much does asthma limit your choices?

Take this short quiz to find out.

Learn more about BT with this FREE DVD for patients with asthma.



Do your asthma patients know what they are missing?

Now, a revolutionary procedure can help them lead a fuller life.

Frequent asthma exacerbations can have a profound impact on a patient's lifestyle. Severe asthma places limitations on work, school, and other activities. However, patients may not acknowledge—or even recognize—that their asthma symptoms are severe. Over time, these patients may try to avoid exacerbations by modifying daily activities—even those that they enjoy.

Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe, minimally invasive outpatient procedure for the treatment of severe asthma in adults. If you have patients who you believe may benefit from this procedure, the information in this section will help you identify the appropriate BT candidates.

Who is appropriate for BT?

- Adult patients with severe asthma (at least 18 years old)
- Patients whose asthma is not well controlled despite taking a combination of inhaled corticosteroids and long-acting beta-agonists such as Advair™, Symbicort™, or Dulera™
- Patients able to safely undergo bronchoscopy per hospital guidelines

Help your patients recognize severe asthma: The online **Asthma Impact Survey** is intended to help you determine how asthma may be influencing the choices your patient makes every day.

A recent study has shown that the interference of asthma with daily activities is a key predictor for the risk of future exacerbations.[1] In fact, in an analysis of the quality-of-life survey you see here, patients with severe health impairment related to asthma were 70% to 4 times as likely to manifest adverse outcomes like ER visits and oral corticosteroid use.[2]

Who is *not* appropriate for BT?

- Patients who have a pacemaker, internal defibrillator, or other implantable electronic device
- Patients who have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines
- Patients who have previously been treated with BT

BT should be delayed when any of the following conditions are present:

- Active respiratory infection
- Asthma exacerbation or changing dose of systemic corticosteroids (up or down) in the past 14 days
- Known coagulopathy

EXHIBIT 7
WIT: Opposer
DATE: 4/9/15
MAUREEN O. POLLARD

Patient is unable to stop taking anticoagulants, antiplatelet agents, aspirin, or non-steroidal anti-inflammatory medications (NSAIDS) before the procedure with physician guidance

Who performs the BT procedure?

Pulmonologists who are experienced in bronchoscopy

BT training is required, and includes:

- Review of Alair System Catheter Directions for Use and Controller Operator's Manual
- Guided didactic instruction in computer simulation-based Bronchial Thermoplasty Learning Center
- Detailed in-service training of the Alair System
- Hands-on training with Alair System in a lung model prior to initial cases
- Proctoring of initial cases by Boston Scientific Health Care Industry Representative (HCIR)
- Ongoing support of cases when requested

Where is the procedure performed?

At facilities that are appropriately equipped to perform bronchoscopy and are equipped to handle respiratory emergencies

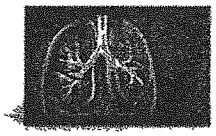
How is the procedure performed?

Click here to view the video

Review a complete list of **indications for use, contraindications and precautions**.

If you would like to refer a patient for BT or are interested in performing the procedure yourself, please complete the **Physician information request form**.

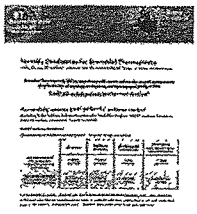
References.
1. Schatz M, et al *Chest* 2012;41:66-72
2. Schatz M, et al *J Allergy Clin Immunol.* 2011;128;1:44-49.e1.



See how BT works

View an animation of the BT procedure in: **English**, **Français**, **Deutsch**, **Italiano**, or **Español**

Find out why physicians are excited about bringing BT to patients with severe asthma.



Help your patients recognize severe asthma by

Physician information request

If you would like more information on Bronchial Thermoplasty (BT), please complete the information requested below and a representative from Boston Scientific will follow up with you.

Please select one of the following:
O I am interested in referring patients for Bronchial Thermoplasty treatment.
O I currently provide or am interested in providing Bronchial Thermoplasty treatments to patients.

(* Required)

Title	Please Select...
Specialty	Please Select...
First Name *	
Last Name *	
Hospital/Clinic *	
Address 1 *	
Address 2	
City *	
State *	Please Select...
Zip/Postal code*	
Country	
Phone	
Email *	
I currently perform bronchoscopy	O Yes O No
I perform approximately the following number of bronchoscopies per month	Please Select...
I see in my office the following number of severe asthma patients per month	Please Select...
How did you hear about us? *	Please Select...

☐ I am interested in learning more about the BT training program

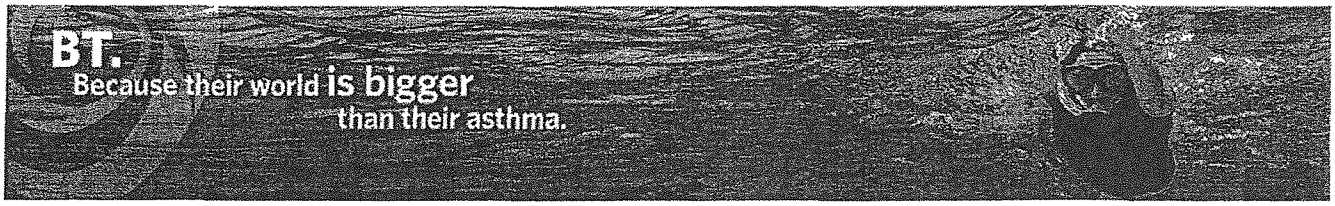
☐ I am interested in referring a patient(s) for BT

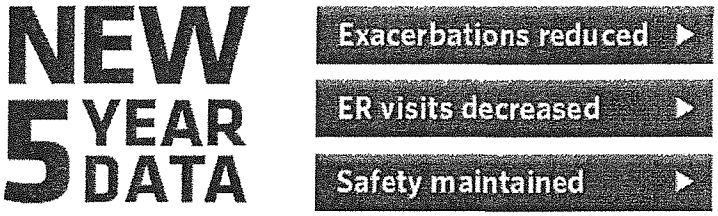
☐ I would like to receive more information on BT

Comments:

Submit

Boston Scientific Corporation
150 Baytech Drive
San Jose, CA 95134
T: 877-810-6060 F: 408-419-0199





Established long-term effectiveness and safety:
5 years of clinical trial follow-up data
12+ years of clinical experience

Asthma Intervention Research 2 (AIR2) Trial: At 1 year, patients with severe asthma showed significant improvement in their asthma-related quality of life after treatment with Bronchial Thermoplasty (BT) delivered by the Alair™ System:

- Quality of life improvement: 79% of patients who were treated with BT reported a significant improvement in their asthma-related quality of life[1]
- Fewer absences: 66% fewer asthma-related days lost from work, school, and other activities, compared with sham-controlled patients[1]

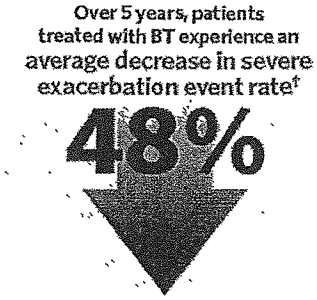
AIR2 Trial 5-Year Extension Study: This study evaluated the sustained effectiveness of BT beyond 1 year, and the safety of BT out to 5 years in the BT-treated patients from the AIR2 Trial.[2]

Fewer exacerbations, with effectiveness maintained out to 5 years

32% decrease in severe asthma exacerbations (requiring systemic corticosteroids) at 1 year, compared with sham-controlled patients[1]

Reduction in exacerbations seen at 1 year maintained out to 5 years[2]

—44% average decrease over 5 years in the percentage of patients having severe exacerbations, compared with 1 year prior to BT treatment[2]



n = 162 (85% retention at Year 5)
†Events per patient per year; compared with 12 months prior to BT treatment

5-year reduction in severe exacerbations requiring systemic corticosteroids

The decrease in severe exacerbations over 5 years included a substantial reduction in the use of systemic corticosteroids associated with those exacerbations[2]

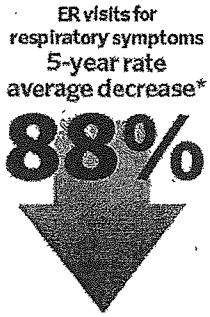
Fewer asthma exacerbations means reduced need for the associated oral steroid treatment and its side effects

Fewer emergency room visits, with reduction maintained out to 5 years

84% reduction in emergency room visits for respiratory symptoms at 1 year, compared to sham-controlled patients[1]

Reduction in ER visits seen at 1 year maintained out to 5 years[2]

—78% average decrease over 5 years in the percentage of patients experiencing ER visits for respiratory symptoms, compared with 1 year prior to BT treatment[2]



n = 162 (85% retention at Year 5)
*Events per patient per year; compared with 12 months prior to BT treatment

Safety maintained over 5 years

No increase was seen in hospitalizations, asthma symptoms, or respiratory adverse events over the course of 5 years[2]

No structural changes in airways that were clinically significant were due to BT at 5 years (based on high-resolution HRCT review)[2]

No clinically significant deterioration in lung function (FEV_1) at 5 years[2]

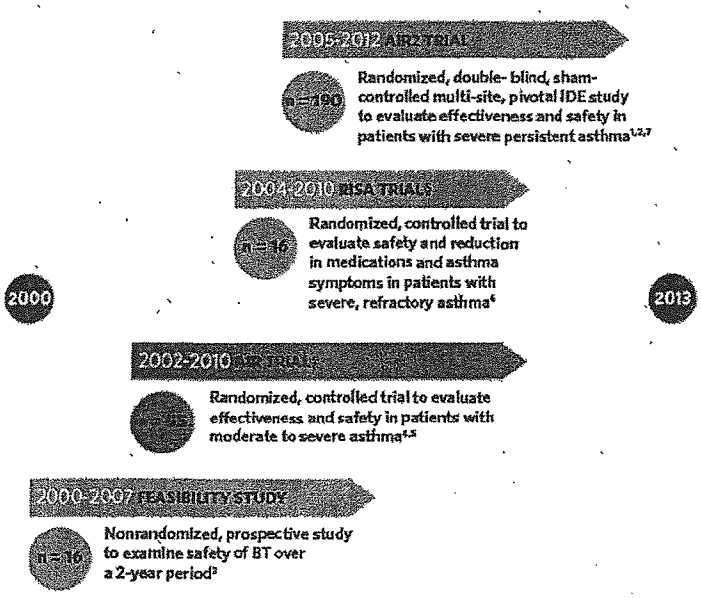
As with any procedure, there are risks, and individual results may vary. The most common adverse event of BT is a temporary worsening of respiratory-related symptoms. These events typically occur within one day of the BT procedure and usually resolve within a week with standard care. There is a small risk (3.4% per procedure) that symptoms may require hospitalization.

CLICK HERE TO VIEW 5 YEAR DATA PUBLICATION

Clinical studies for BT

BT has been studied in a rigorous, stepwise fashion beginning with animal studies, followed by 4 clinical studies in asthma patients, 3 of which were randomized, controlled clinical trials, and all with 5 years of follow-up. Two clinical studies focused on the severe asthma patient population.

The **Asthma Intervention Research 2 (AIR2) Trial** is one of the largest sham-controlled medical device trials in pulmonary medicine. At 1 year, patients with severe asthma treated with BT showed significant improvement compared to sham-controlled patients.[1,2]



‡ Asthma Intervention Research (AIR)

§ Research in Severe Asthma (RISA)

Selected studies are shown below. Click on the individual trial name below for additional information on each clinical study.

AIR2 Trial

RISA Trial

REFERENCES:

1. Castro M, et al, for the AIR2 Trial Study Group. *Am J Respir Cnt Care Med.* 2010:181:116-124.
2. Wechsler M, et al; for the AIR2 Trial Study Group [published ahead of print September, 2013]. *J Allergy Clin Immunol.* doi:10 1016/j jaci 2013 08 009.
3. Cox G, et al *Am J Respir Crit Care Med* 2006;173.965-969.

4. Cox G, et al *N Engl J Med.* 2007;356 1327-1337.

5 Thomson N, et al, for the AIR Trial Study Group. *BMC Pulm Med.* 2011;1-9

6 Pavord I, et al. and the RISA Trial Study Group. *Am J Respir Care Med* 2007;176:1185-1191.

7. Castro M, et al, for the AIR2 Trial Study Group. *Ann Allergy Asthma Immunol.* 2011;107.65-70.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Opposition No. 91215699

In the matter of Application Serial No.:
85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
Published in the Trademark Official Gazette
on December 3, 2013

****

Boston Scientific Corp. and
Asthmatx, Inc.,

Opposers,

v.

Holaira, Inc.,

Applicant.

****

DEPOSITION OF MATTHEW W. SPRAGUE

Thursday, April 9th, 2015

1:57 p.m.

Held At:

Latham & Watkins, LLP

200 Clarendon Street

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR #149108

APPEARANCES:

FOR THE OPPOSERS:

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bwalz@winthrop.com

FOR THE APPLICANT:

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612-607-7000
dhansen@oppenheimer.com

INDEX

E X H I B I T S

NO.	DESCRIPTION	PAGE

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NO EXHIBITS WERE MARKED

P R O C E E D I N G S

MATTHEW W. SPRAGUE,
having been first duly identified and sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. WALZ:

Q. Thank you, Matt, thanks for taking the time to be part of this.

Just to give you a little background on the structure before we get started. So Dennis and I have an agreement whereby I'm going to have the first opportunity to take your direct testimony.

A. Okay.

Q. Once that's complete, Dennis will have an opportunity to cross-examine you. And then following his cross-examination, I'll have an opportunity to do any redirect on your testimony.

A. Okay.

Q. So not that there are any surprises, but that will be the structure for the day.

So could you -- by the way, before we start, if you do need to take a break or you

want to take a break, please let us know. We were flexible with Karen, we'll be flexible with you. I guess the only caveat to that is if you're in the middle of an answer, we'd like you to finish the answer, and then we can break after that.

A. Okay.

Q. So would you mind saying your name and spelling it for the record?

A. Sure. Matthew Sprague, M-A-T-T-H-E-W, S-P-R-A-G-U-E.

Q. And what is your education?

A. I have a finance degree, and an MBA.

Q. From what university?

A. My undergrad is at Bryant University, and my MBA is at Babson.

Q. And what degrees did you obtain from each?

A. Bachelor of science at Bryant, and it was a Master's in business administration at Babson.

Q. Any emphasis on the MBA?

A. No.

Q. What was your work experience prior to Boston Scientific?

A. Coming out of school, I worked for a large computer company called Digital Equipment Corporation as a financial analyst, spent five years there.

Then I went to what you call a telecommunications OEM, we made hardware and software. I was financial manager. I handled some sales training, financial planning and analysis, generally a finance role there for approximately three years.

And then Boston Scientific.

Q. Okay. And when did you start at Boston Scientific?

A. 2003.

Q. And what positions have you held at Boston Scientific?

A. I started in our, what we call our corporate FP&A group, our financial planning and analysis group, so I was the manager of revenue and gross margin analysis, manager of strategic planning.

And then about six years ago I moved to the current division that I lead now at the endoscopy division as a manager, and I've had a couple of roles since then. And now I'm the

controller of that group, which is to say the head of finance for the division.

Q. Okay. And with respect to each position that you've held at Boston Scientific, approximately how much time have you spent in each role?

A. So I've been in two groups, if you will, one for five years and then one for six years. In the first group that I was in for five years, I probably averaged 18 months within each role, but again within the same group, so I just did a different position within that, same manager, same group. And then I've had three titles in six years, but again, same group within endoscopy. So about two year average in each stint, if you will, although I've been in this job just over a year.

Q. Okay. And what were your job duties with each position you held at Boston Scientific?

A. Going back to 2003?

Q. Yes.

A. Job duties. So in my first role I was responsible for reporting and analysis of revenue for sales. I was responsible for

analyzing our gross margins, so understanding the drivers of things like price, or what impacts our gross margins, meaning revenue minus the cost of that good that we sold gets you to gross margin, so responsible for that.

I implemented -- or I helped, I led a team, I was on a team to help implement financial planning systems.

I helped to do some acquisition analysis, and actually complete some acquisitions.

Then when I moved over to endoscopy I started off as -- I think my title was senior manager of FP&A, financial planning and analysis, so budgeting, forecasting, planning for the group, as well as what we call general accounting, closing the books. More acquisition analysis. More -- you know, we bought Asthmatx, so that was some of my role, and I continue to do that now.

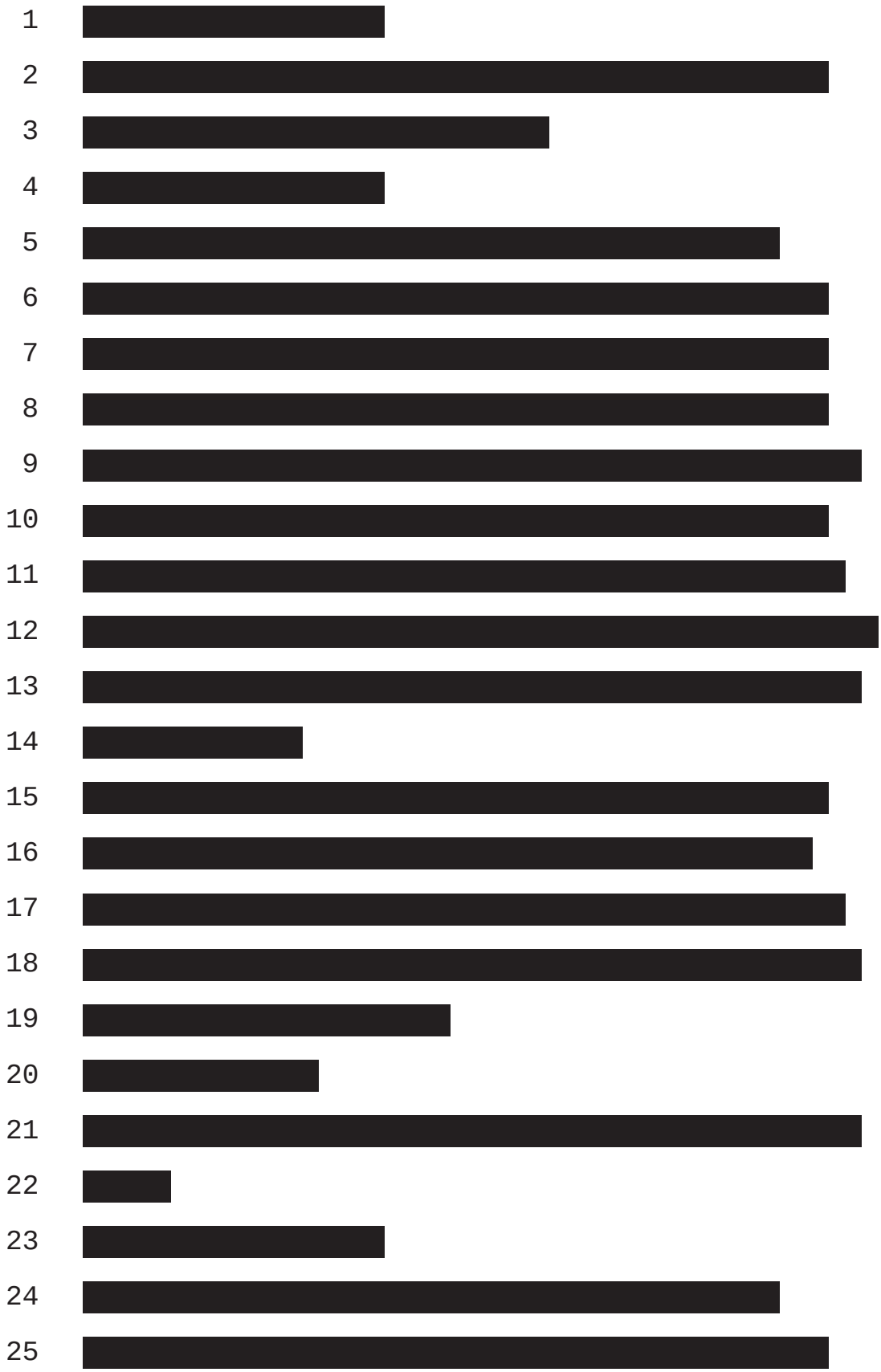
Business partner, if you will, to other functions within the group to help them with, again, make decisions, financial analysis, things like that.

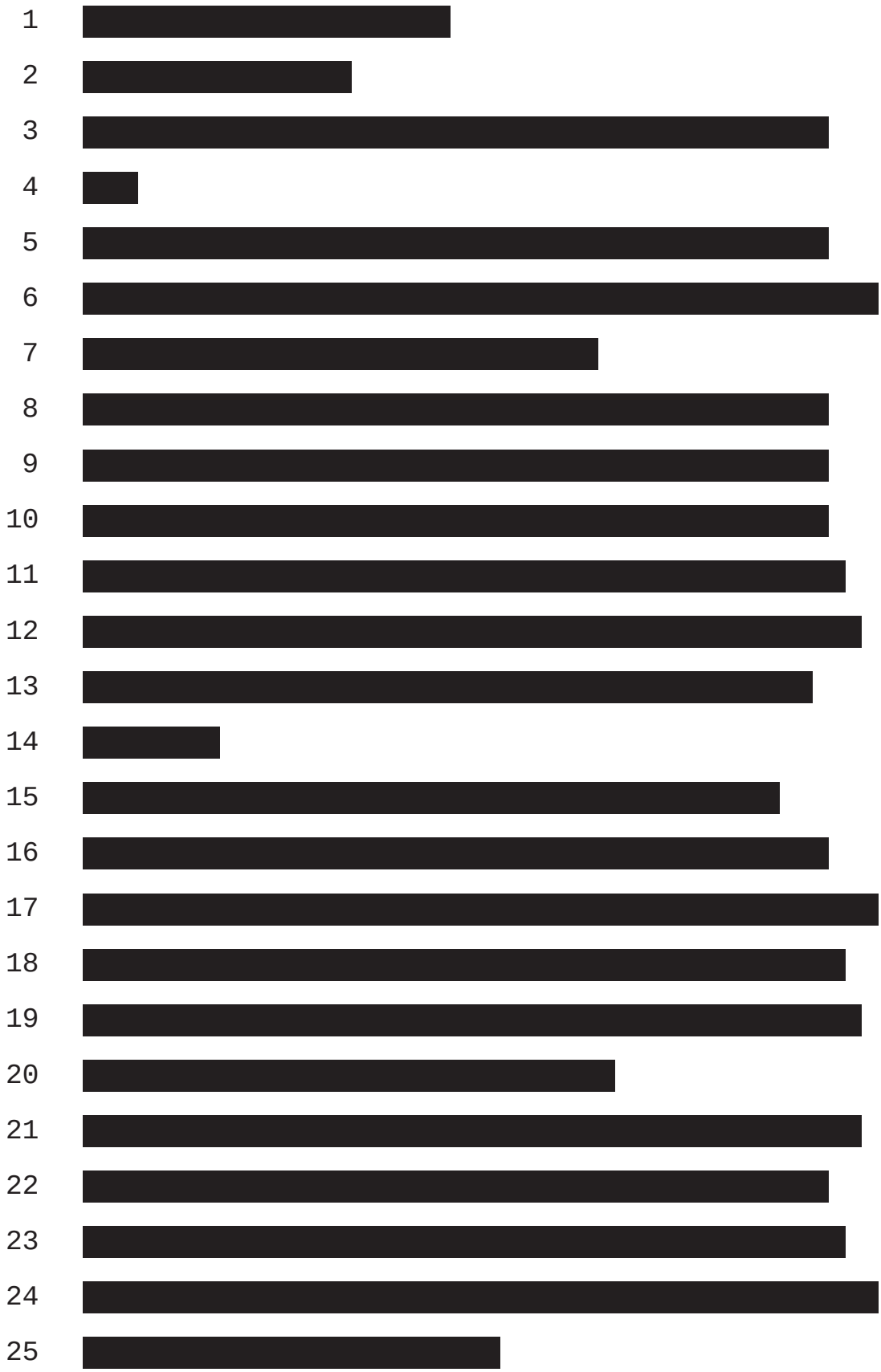
Q. So your role as the partner is just to

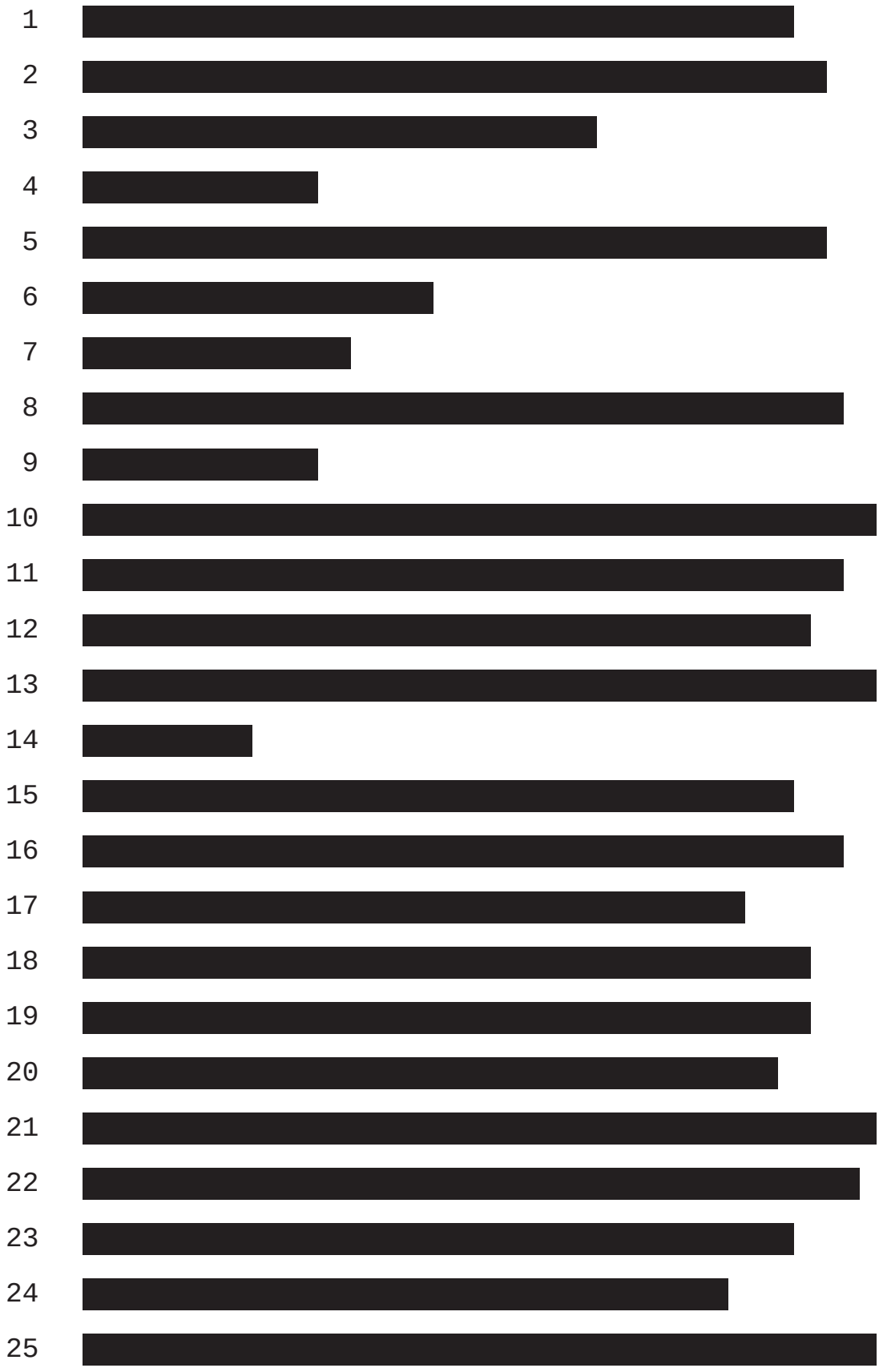
provide the financial guidance?

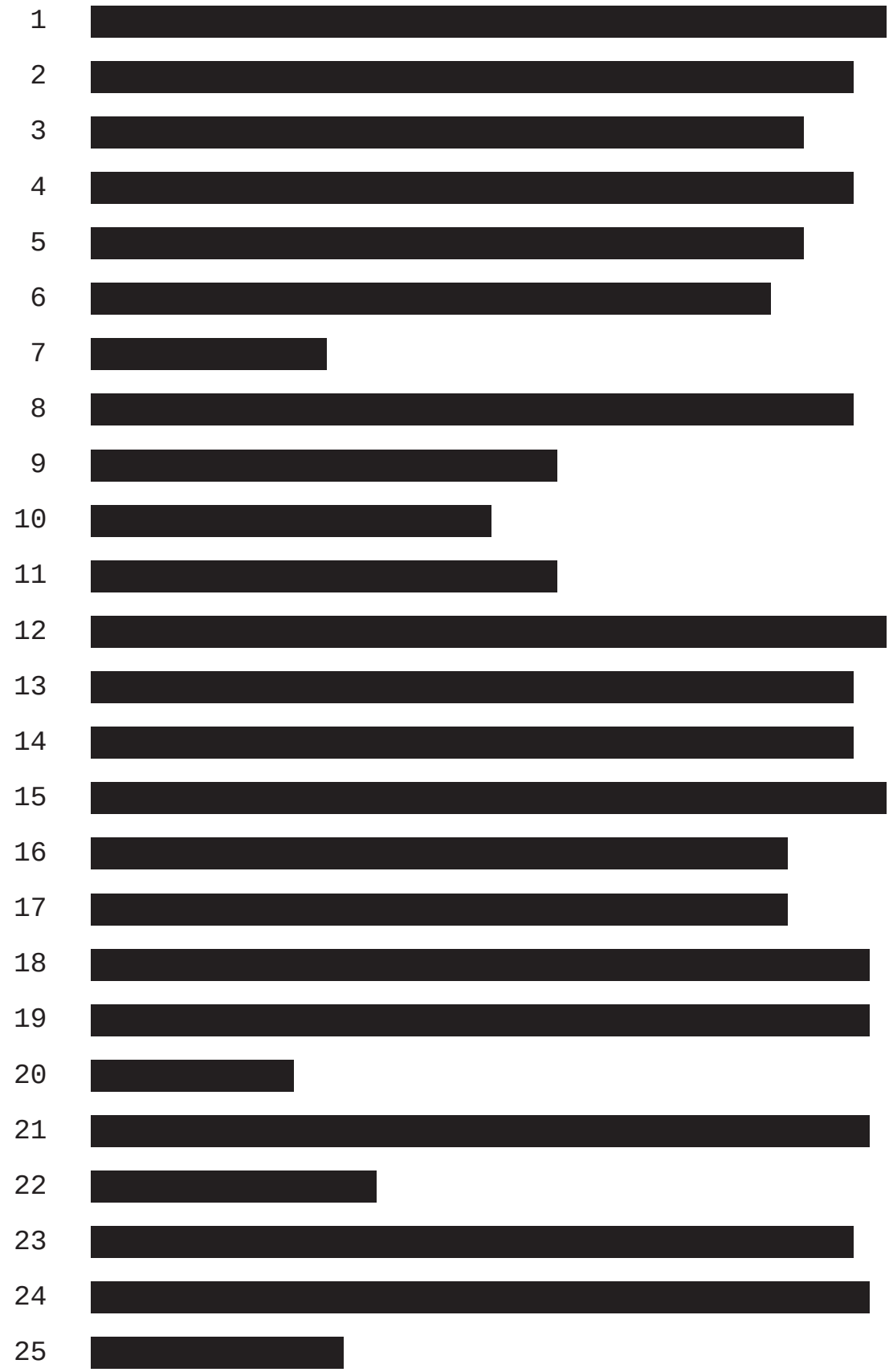
A. Guidance, yes.

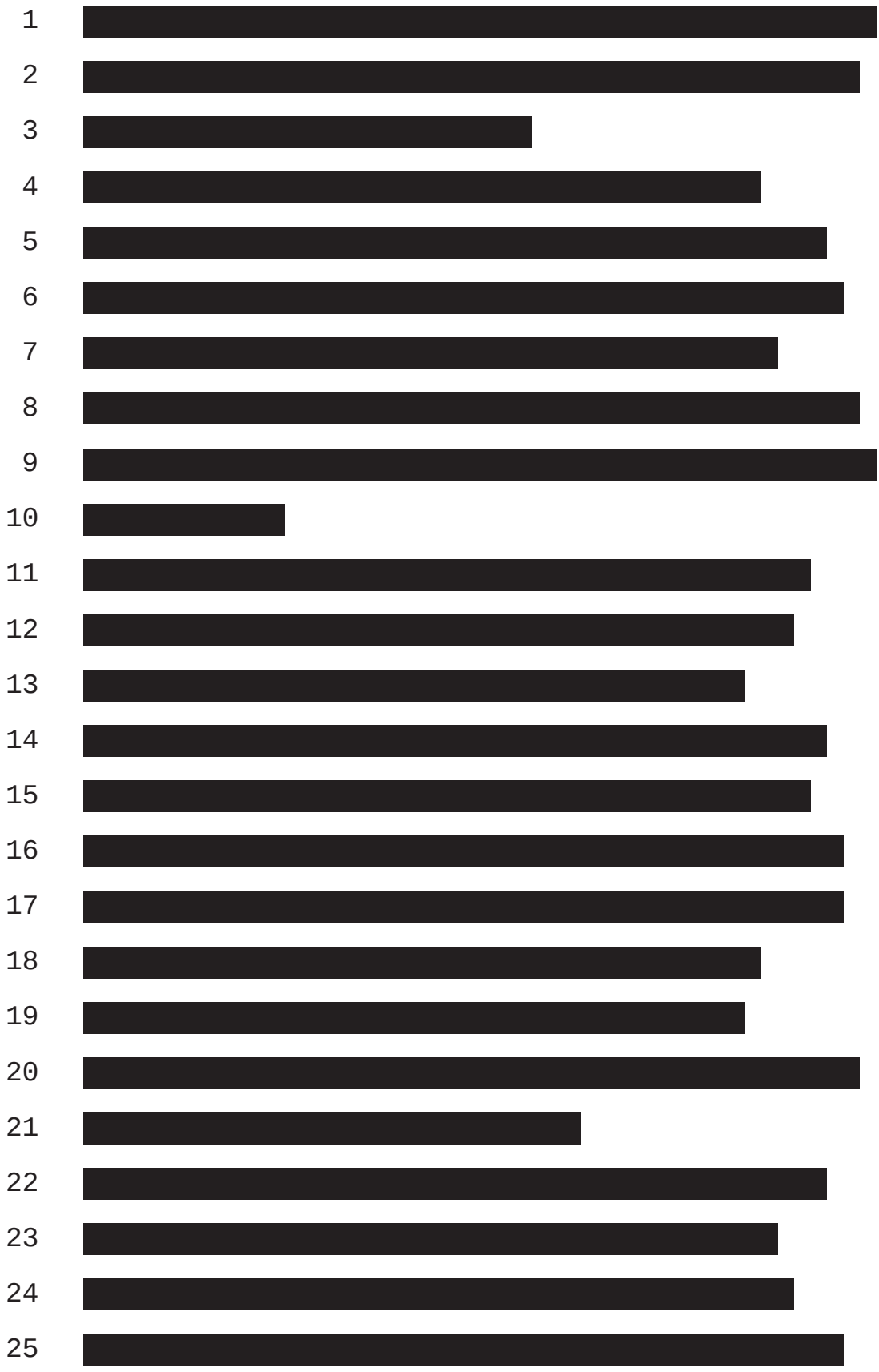
[redacted]











[redacted]

[redacted]

Q. Okay. What would the impact be on the sales figures if another BT therapy was offered?

MR. HANSEN: Objection. Calls for speculation, hypothetical.

BY MR. WALZ:

Q. You can answer.

A. Bronchial thermoplasty meaning the application of energy to smooth muscle tissue?

Q. The treatment, right.

A. Potentially it would lessen our sales because there would be another competitor and another option out there.

MR. WALZ: I have no further questions.

CROSS EXAMINATION

BY MR. HANSEN:

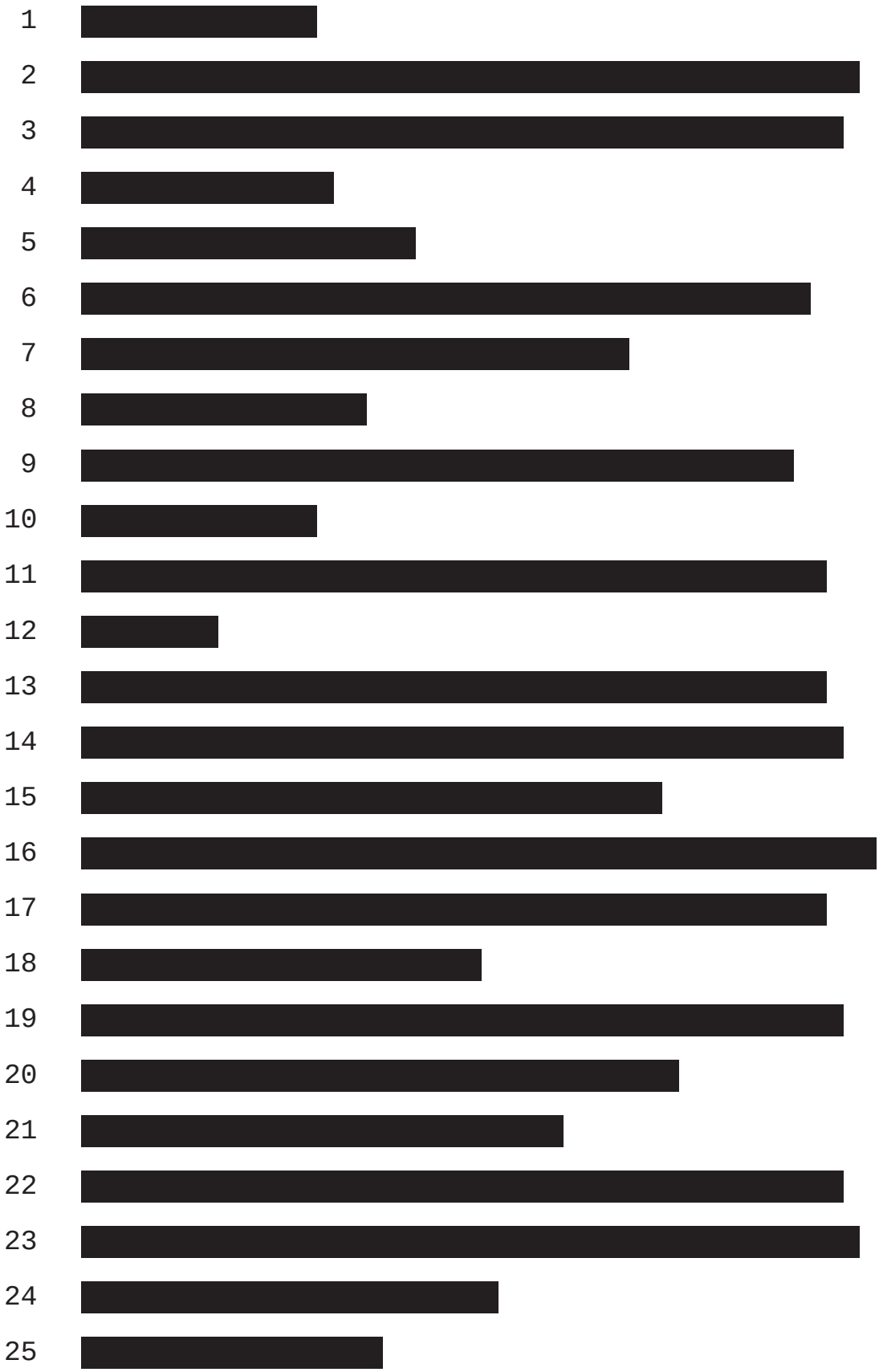
Q. Mr. Sprague, did I pronounce that correctly?

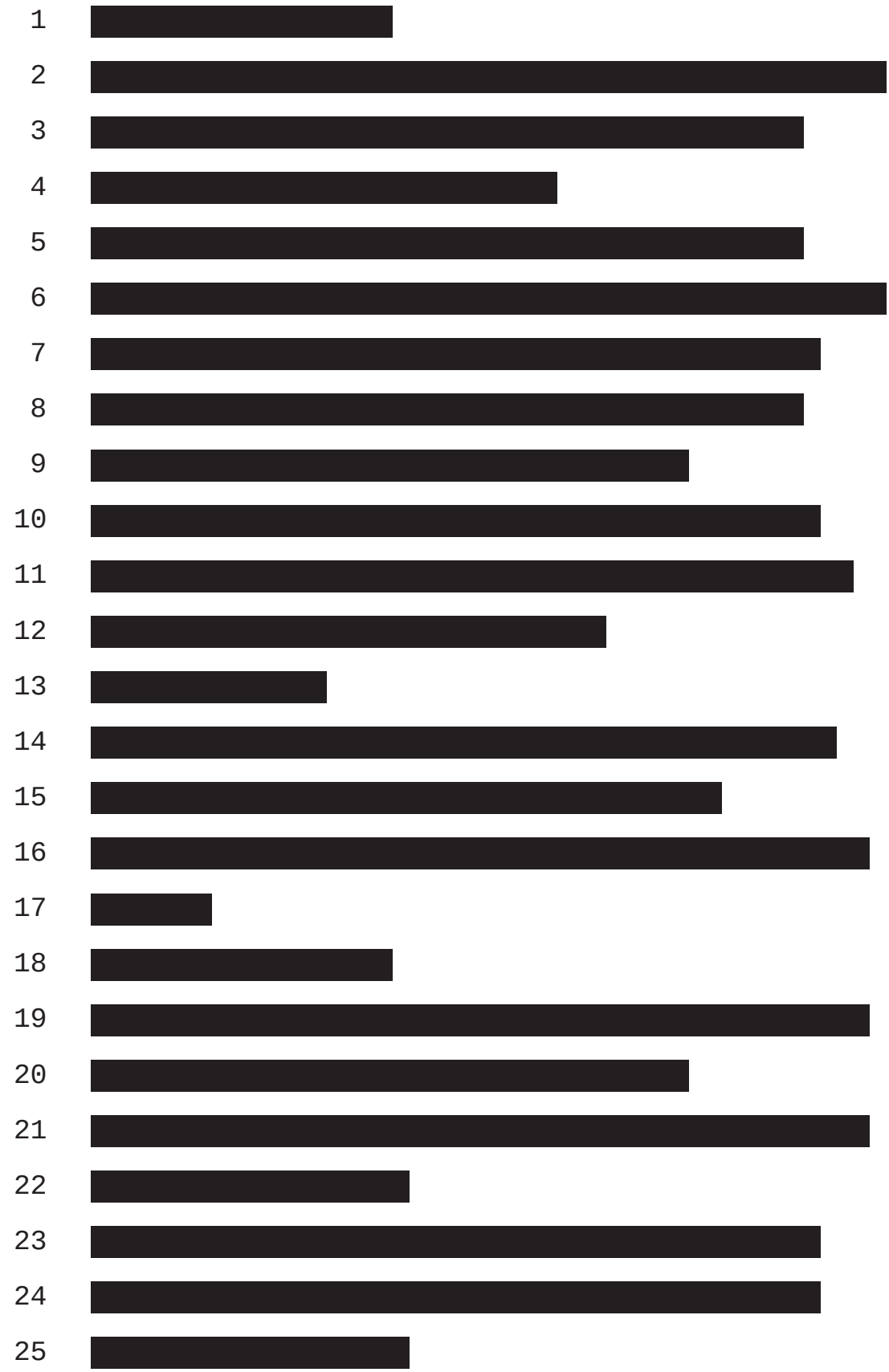
A. Yeah, you did. Thank you.

Q. Great. I'm actually pretty bad at that, so I'm glad I got it right.

[redacted]

[redacted]





[redacted]

Q. Sales representatives, you talked about sales representatives briefly, right?

A. Yes.

Q. And you attributed their work to being impactful to the revenue numbers, right?

A. Yes.

Q. And with respect to Boston Scientific's products, including the Alair product, sales representatives are critical to the promotion and sale of those products, correct?

A. Correct.

Q. They're important because they have relationships with the physicians who decide to purchase the product, right?

A. Yes, they do.

Q. And those sales representatives train those physicians on how to use the product?

A. In some cases, yes.

Q. And with respect to the Alair System?

A. It's not the only source of training, but yes, the sales reps do demonstrate its use.

Q. Okay. You discussed a five year -- well, maybe I'm mischaracterizing it, but a five-year strategic plan?

A. Correct.

Q. Is that kind of what it's called within the business, five-year strategic plan?

A. Yes.

Q. And that has projected sales figures out for the next five years?

A. Correct.

Q. When was that strategic plan created?

[redacted]

Q. Okay. And when was the prior iteration to May of 2014?

[redacted]

[redacted]

[redacted]

Q. And did you provide that to your counsel to produce in discovery in this case?

A. No, I did not.

Q. Okay. Did you review that in preparation for your testimony today?

A. No.

Q. Is that something you just look at in the regular course of your job duties?

A. Yeah, it's something I helped to produce, so yes.

MR. HANSEN: I don't think I have any more questions for you, Mr. Sprague.

MR. WALZ: None for me.

(Whereupon, the deposition was concluded at 2:22 p.m.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 9th day of April, 2015, at 1:57 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.

In witness whereof, I have hereunto set my hand this 19th day of April, 2015.

Maureen O Pollard

MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A
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ACKNOWLEDGMENT OF DEPONENT

I, Matthew Sprague, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

MWS 26-May-2015

MATTHEW W. SPRAGUE DATE

Subscribed and sworn
To before me this
26th day of May, 2015.
My commission expires: October 8, 2021

Cathleen Dyer

Notary Public

CATHLEEN DYER
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
October 8, 2021

LAWYER'S NOTES

PAGE	LINE	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Boston Scientific Corporation and Asthmatx, Inc.	)	
Opposers,	)	
v.	)	
	)	Opposition No. 91215699
Holaira, Inc.	)	
Applicants.	)	

CERTIFICATE OF SERVICE BY MAIL

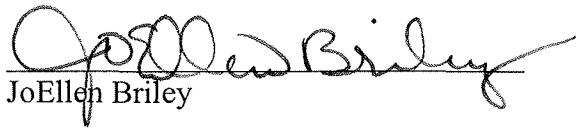
STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

JoEllen Briley, of the City of Minneapolis, County of Hennepin, in the State of Minnesota, states that on the 5th day of August, 2015, she mailed by First Class mail, a cd containing true and correct copies of:

1) Redacted transcript, unredacted transcript, and exhibits for the deposition of Karen Passafaro; acknowledgement and errata sheet signed by Karen Passafaro; and
2) Redacted and unredacted transcript of the deposition of Matthew Sprague; acknowledgement signed by Matthew Sprague (no errata sheet, no exhibits).

in the above-captioned action to the following last known address of record for Applicant, to-wit:

Barbara J. Grahn
OPPENHEIMER WOLFF & DONNELLY LLP
200 Campbell Mithun Tower
222 South Ninth Street
Minneapolis, MN 55402-3338



JoEllen Briley

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